HUMANE CARE FOR ANIMALS IN RESEARCH

HEARING

BEFORE THE

SUBCOMMITTEE ON
HEALTH AND THE ENVIRONMENT

OF THE

COMMITTEE ON
ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

NINETY-SEVENTH CONGRESS

SECOND SESSION

ON

H.R. 6928

TO PROMOTE THE DEVELOPMENT OF NONANIMAL METHODS OF RESEARCH, EXPERIMENTATION, AND TESTING, AND TO ASSURE HUMANE CARE OF ANIMALS USED IN SCIENTIFIC RESEARCH, EXPERIMENTATION, AND TESTING

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HUMANE CARE FOR ANIMALS IN RESEARCH

THURSDAY, DECEMBER 9, 1982

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10:02 a.m., in room 2322 Rayburn House Office Building, the Hon. Henry A. Waxman (chairman) presiding.

Mr. WAXMAN. The meeting of the subcommittee will please come to order. We would like to welcome all of our guests who are here today.

This morning we will receive testimony on H.R. 6928, the Humane Care and Development of Substitutes for Animals in Research Act. This legislation is sponsored by our good friend and colleague Doug Walgren, who has taken a leadership role on this issue.

There is a considerable degree of public interest in the two primary goals of H.R. 6928: First, improving the conditions under which animals are used in biomedical research; and, second, encouraging research into new methods which will enable a reduction in the use of animals.

Clear ethical questions are raised when animals are unnecessarily subjected to pain and discomfort. Callous treatment unrelated to legitimate research aims cannot be tolerated. Such practices are alien to our society and are not consistent with the scientific process.

In many areas of science, the use of animals is our most reliable method of research. However, efforts which will improve the reliability or efficiency of biomedical research should be encouraged.

A Federal research policy which actively pursues alternatives to the use of animals is a reasonable goal and is consistent with this country's commitment to unfettered scientific inquiry. Such research could produce improved scientific techniques such as tissue cultures, bacterial and other nonanimal models and computer simulations. These techniques could lead to more efficient and more productive science.

We must, however, be cautious. In our desire to establish reasonable requirements for the humane care of animal subjects, we must be vigilant not to unreasonably restrict legitimate scientific inquiry. We cannot establish a policy in which rights accorded to animals take precedence over the need to conquer disease and illness.

This morning I hope the subcommittee will obtain a better understanding of the current regulatory and research policies and the

effects of proposals to improve existing standards for the care and treatment of animals. We will hear from a diverse group of witnesses on these subjects.

Before I call on our first witness to talk about H.R. 6928 and proposals that are related thereto, I would like to recognize Congressman Ed Madigan, the ranking Republican member of our subcommittee.

Mr. Madigan.

Mr. MADIGAN. Mr. Chairman, thank you very much.

At the outset I want to thank all of the witnesses who have come to our hearing today to discuss H.R. 6928. I look forward very much to hearing their views on the care of reseach animals and the use of alternative models.

As the chairman has indicated, the use of animals in medical research and testing is an important and sensitive issue that deserves our full and careful consideration. The health benefits that have been derived from animal experimentation are numerous and should be acknowledged by us. However, if there are abuses of animals being used in research, then we should know about that as well.

I anticipate that the testimony of our witnesses will represent the academic research community and the animal welfare community will be most valuable as we evaluate the bill before us. Let me thank all of you for taking the time to appear before our subcommittee to share your opinions on the current condition.

Mr. WAXMAN. Thank you, Mr. Madigan.

We have listed as our first witness a member of our own subcommittee, and rather than have him testify as a witness I would like to have him explain the bill to us as a colleague on our subcommittee, and as the leading proponent of legislation in this area.

It is my pleasure to recognize Congressman Doug Walgren.

STATEMENT OF HON. DOUGLAS WALGREN

Mr. WALGREN. Thank you, Mr. Chairman.

I would like this statement to be considered as testimony very strongly in favor of this bill. I would like to give this statement in that light.

We have, Senator Melcher, who is here and who will be following my statement, and also other Members of Congress who will be submitting testimony along with the other witnesses in support of the bill.

At the start, I want to express my real appreciation and respect for you, Mr. Chairman, for scheduling this hearing in the pressure of the time demands that the closing days of Congress entail for everyone. I think that is a measure of the importance of this issue and a statement about how this issue is one of great concern to the public. There are balancing questions that are very delicate and important to strike. That is to say, it is most important that we deal with these issues and think about them thoughtfully.

The bill that we are talking about today is entitled The Humane Care and Development of Substitutes for Animals in Research Act. It has come a long way toward becoming law, and this hearing in the Health Subcommittee is an important step in that process.

This legislation started its development several years ago in the Science and Technology Committee's Subcommittee on Science, Research, and Technology, which I chair. We had several days of hearings in October 1981 on the use of animals in research in testing, and at that time we heard testimony on a number of proposals that have been made in this area. The hearings clearly pointed to needs which we on the Science and Technology Committee felt should be addressed by law.

This bill moved through the Science and Technology Committee as a consensus bill. It passed my subcommittee without dissent. It passed the full committee with several dissents, but there was very broad support. We have at all times tried to incorporate the reservations that both sides in this particular issue have had.

Nonetheless, our hearings did indicate that there is a need for more emphasis on developing and using nonanimal research methods or methods which would require the use of fewer animals. There was demonstrated a need for a disciplined evaluation of the justification of pain in the process of research in terms of the value of the research, and there was the demonstrated need for broad assurance of the public that where animals are used in research that uniform, accepted, and humane standards of care can be depended on.

The bill that resulted from this process has much to recommend it. Wide segments of both the scientific research and the animal welfare communities support this bill, and it reflects a number of contributions from both sides. One of the early concerns was the procedures contained in an earlier version of the bill for identifying nonanimal research proposals as candidates for awards under title I of the bill. There was concern that this would interfere with the scientific review process and skew the awards away from scientific research that would, when decided on the merits, compel the allocation of our effort at this time.

We worked with representatives of the research community and changed the language to clarify that the role of the advisory panel to the Secretary is to advise and recommend, and it is a way of structuring consideration of the value of the efforts that could be made in nonanimal research rather than any setting aside or taking away from research priorities as they are evaluated by the scientific review panels.

I would like to mention another example. When the research community raised the legitimate concern that the 3-year accreditation requirement contained in earlier proposals would place a financial burden on many institutions, we built in a longtime period and emphasized that waivers of this provision would be provided in cases of undue hardship. The bill now provides that research entities may spread over 10 years, their expenses in coming up to what is a present and broadly used standard of care.

A similar bill has been introduced in the Senate by Senator Dole which calls for a 1-year study by the Secretary of Health and Human Services before regulations under Title II are issued to determine the degree of impact of the accreditation requirement on research facilities using animals. I think that we certainly would want to consider that kind of reasonable approach before regulations have a strict impact.

At present, the only statutory standards for animal laboratory care are contained in the Animal Welfare Act. This act, as you know, is administered by the U.S. Department of Agriculture Animal and Plant Health Inspection Service, which has historically operated on an extremely limited and clearly inadequate budget as far as laboratory animal inspection is concerned.

That act has fallen far short of assuring a uniform, humane standard of care and treatment. It is the lack of this assurance that there is a uniformly enforced standard that worries those who are concerned with the welfare of research animals. The requirement contained in this bill that a research entity doing research with Federal funds be accredited for proper standards and that it maintain an animal studies committee with real responsibility for keeping an eye on conditions in the laboratory will go a long way toward alleviating those concerns, both in terms of solving a problem which we now attempt to solve by external, invasive inspection by a Federal inspector coming into the laboratory, and at the same time doing it in a way that will encourage the right things to happen within the laboratory by their own initiative.

As to the concern of having an outside or unaffiliated member on the animal studies committee, I think we should point out that the institution itself chooses that person and presumably would do so with great care.

When Dr. Raub of the National Institutes of Health testified before our Science Subcommittee last May, in speaking of animal care committees, he stated:

> As NIH moves to refine its guidelines in this area in the coming months, we plan to specify that at least one veterinarian and one non scientist serve regularly on awardees' animal care committees.

And we know that the best institutions do maintain animal care committees, some of which already have outside members.

I would like to add that in general this bill puts a floor under much present practice which we find consensus on. For example, of the 660 private institutions now doing research with Federal funds, 460 already have animal care committees and so the requirement of an animal care committee really broadens the present good practice and helps it to accomplish the ends which I think the public has a right to rely on.

Many scientists and other professionals who work with animals in laboratories have said to us that they already have in place most of the requirements, and this is certainly commendable. But it also should convince us that having such requirements made mandatory is not an unreasonable request because we are dealing with laboratories across the board.

This bill is not designed to be costly or burdensome with respect to redtape. Most researchers agree that good laboratory practices are consistent with good science and the bill calls for only those measures which insure good practices. I think the truth of it is that having this kind of internal, upgraded system in place will help assure those in the research community that they can effectively compete for limited dollars in the modernization of their laboratories.

It is very important that laboratories reach accepted minimum standards before money is allocated to couches for student lounges in universities, and the like. So this kind of a basic floor of good practice would only be helpful for the research community and, I think, as has been testified, to assure good research results in the process.

Animals that are not well cared for do not give accurate research results no matter what the experiment. So I would just like to say in closing that my colleagues on the Science and Technology Committee who have developed this legislation believe it is a good bill. It is a bill that can be supported as reasonable and helpful to deal with this kind of question and assure the public that the basic standards of humane care do exist in the Federal research establishment.

I appreciate the opportunity to make those somewhat detailed opening remarks, but this is an area where absolutes have been raised in the legislative process. Someone once said, "It is either you or Fido." Well, that is not the question at all. This bill walks a line that I think assures the very considerations that the chairman and other members are most concerned about in the scientific community and we want to recommend it to you.

Thank you, Mr. Chairman.

[Testimony resumes on p. 26.]

[The text of H.R. 6929 and agency report follow:]

I

97TH CONGRESS
2D SESSION

H. R. 6928

To promote the development of nonanimal methods of research, experimentation, and testing, and to assure humane care of animals used in scientific research, experimentation, and testing.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 4, 1982

Mr. FUQUA (for himself, Mr. WALGREN, Mrs. HECKLER, Mr. BROWN of California, Mr. ROE, Mr. LUNDINE, Mr. DYMALLY, Mr. FISH, Mr. SCHEUER, Mr. CARNEY, Mr. YOUNG of Missouri, Mr. ERTEL, Mr. FAUNTROY, Mr. LANTOS, Mr. JACOBS, Mr. WYLIE, Mr. MOFFETT, and Ms. MIKULSKI) introduced the following bill; which was referred jointly to the Committees on Energy and Commerce and Science and Technology

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A BILL

To promote the development of nonanimal methods of research, experimentation, and testing, and to assure humane care of animals used in scientific research, experimentation, and testing.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SHORT TITLE

SECTION 1. This Act may be cited as the "Humane Care and Development of Substitutes for Animals in Research Act".

FINDINGS

SEC. 2. The Congress finds that—

(1) the humane care of animals used in scientific research and testing should be assured as part of a respect for life, and the public interest in this matter should be respected;

(2) methods of testing that do not use animals have been developed which show promise of being faster, cheaper, and more accurate than traditional animal experiments for some purposes; and further opportunities exist for the development of these methods of testing;

(3) measures are needed to assure that where animal experimentation is necessary, treatment, care, and experimental methods and practices are such as to limit animal pain and distress to a minimum;

(4) institutional arrangements are needed to recognize the depth of public concern for protection of all life, and the expression of that concern in pressure for measures to minimize pain and distress of laboratory animals, and to improve self-regulating measures which reflect this concern; and

(5) measures which help to meet public concern for laboratory animal welfare are important in assuring that significant areas of science, in which animal ex-

perimentation is crucial, such as research benefiting human health, will continue to progress.

TITLE I—DEVELOPMENT OF IMPROVED RESEARCH AND TESTING METHODS

NONANIMAL TESTING METHODS

SEC. 101. (a) The Secretary of Health and Human Services (hereafter in this Act referred to as the "Secretary") is authorized to make awards—

(1) to sponsor research into, and development of, methods of research, experimentation, and testing which do not require the use of live animals, which reduce the numbers of live animals used, or which produce less pain and distress in such animals than methods currently in use; and

(2) to establish the validity and reliability of such methods for the purpose of replacing animal research and testing methods currently in use, where applicable.

(b) No award may be made under this section unless an application or proposal therefor has been assessed through applicable peer review procedures. Such application or proposal shall be in such form, submitted in such manner, and contain such information, as the Secretary shall by regulation prescribe.

(c)(1) The Secretary shall designate an Advisory Panel to—

(A) provide advice concerning his responsibilities under this section and section 102;

(B) make such recommendations as it deems appropriate to the Secretary concerning specific opportunities or problems regarding research support of nonanimal testing; and

(C) design and recommend a system for insuring that any application or proposal meeting the requirements of this title will receive full consideration for funding by all appropriate programs of the Department of Health and Human Services, or for funding under this title from resources made available in accordance with subsection (d).

(d) Funds for making awards under clauses (1) and (2) of subsection (a) shall be made available by the Secretary by allocation of adequate research resources within the Department of Health and Human Services.

ADDITIONAL RESPONSIBILITIES OF SECRETARY

SEC. 102. (a) The Secretary shall direct the National Institutes of Health, the Food and Drug Administration, and the National Toxicology Program, and shall consult with the Environmental Protection Agency and other appropriate regulatory and scientific research agencies to—

(1) promote the development of new, and the evaluation of existing, testing methods that do not re-

quire the use of animals and which will satisfy public health and safety concerns as well as regulatory requirements;

(2) promote the use of nonanimal methods of research, experimentation, and testing by seeking further cooperation in international regulatory research and development programs that would lead to more effective toxicologic data systems; and

(3) assure the efficient use of current and future research and test data involving animal use by enhancing the capabilities and the integration of data storage and retrieval systems.

(b) The Secretary shall direct the National Toxicology Program to significantly increase its resources for research and development on new methodologies and validation of nonanimal research and testing methods or computer models, which could be more rapid, less expensive, equally or more reliable, and generate more useful toxicological and safety information.

(c) The Secretary shall submit a report to the Speaker of the House of Representatives and President of the Senate not later than two years after the date of enactment of this Act and biennially thereafter setting forth progress under this section, including new initiatives to reduce animal use and

increased emphasis on development of new methodologies by the National Toxicology Program.

TITLE II—FEDERAL AWARD REQUIREMENTS

GENERAL REQUIREMENTS

SEC. 201. No Federal agency shall, after the effective date of this title, conduct within any of its own research entities, or approve any research entity for the receipt of a Federal award for the conduct of research, experimentation, or testing, involving the use of large numbers of animals unless—

(1) that research entity is accredited for such use in accordance with section 202; and

(2) that research entity has provided to the agency the assurances required under section 203.

ACCREDITATION

SEC. 202. (a) In order to be eligible to receive a Federal award for the conduct of research, experimentation, or testing, involving the use of large numbers of animals, a research entity shall provide to the responsible Federal agency evidence that it is accredited as qualified to engage in such use by a recognized accrediting agency approved by the Secretary under subsection (b) of this section. The Secretary shall, by regulation, prescribe the form and manner in which such evidence shall be presented.

(b) For the purpose of accrediting entities for the conduct of research, experimentation, or testing, involving the use of large numbers of animals, the Secretary shall designate (and shall at least once each five years review the designation of) a private agency or agencies which the Secretary has determined to—

(1) have the demonstrated capability to ascertain the qualifications, background, and experience of research entities in the use of animals for such purposes;

(2) have established a system for the initial accreditation of research entities, including a mechanism for monitoring the correction of items of noncompliance;

(3) have established a system for the routine inspection, not less than once each three years, of laboratory animal facilities at any accredited research entity, such routine inspection to include a mechanism for monitoring the correction of items of noncompliance;

(4) have established a set of standards (A) for acceptable animal care, treatment, and use in experimental procedures, including appropriate and reasonable requirements with respect to handling, housing, feeding, watering, sanitation, ventilation, shelter from extremes of weather and temperature, and exercise, and

(B) with respect to other practices described in paragraphs (2) through (4) of section 301; and

(5) have established a mechanism for liaison with the institutional animal studies committees in accredited research entities, and for involvement of such committees in monitoring compliance with the accreditation standards.

(c) The standards established under subsection (b)(4) shall be designed to be eventually at least comparable to the best of current practices in animal care, treatment, and use in experimental procedures as specified in the "Guide for the Care and Use of Laboratory Animals" of the National Institutes of Health. Attainment of compliance with such standards by research entities shall be a prerequisite for full accreditation after a date which is ten years after the date of enactment of this Act, but accrediting agencies may, in accordance with regulations prescribed by the Secretary for the interim period, provisionally accredit research entities which demonstrate (1) satisfactory and continued progress toward attainment of compliance with such standards, and (2) current practices which (A) comply with standards for animal care and treatment under the Animal Welfare Act of 1966 (7 U.S.C. 2131), and (B) include appropriate and reasonable requirements with respect to handling, housing, feeding, watering, sanitation, ventilation, shelter from extremes of weather

and temperature, and exercise, and other practices described in paragraphs (2) through (4) of section 301.

(d) In the event that no private agencies are found able to carry out the accrediting functions of this section, the Secretary shall, in cooperation with other Federal agency heads, establish within the Federal Government an accreditation mechanism to carry out such functions, to be fully supported by appropriate user fees.

ASSURANCES REQUIRED FROM RESEARCH ENTITIES

SEC. 203. (a) In order to be eligible to receive a Federal award for the conduct of research, experimentation, or testing, involving the use of large numbers of animals as required by section 201, a research entity shall provide to the responsible Federal agency a statement of assurances. Such statement shall be submitted at such time and in such manner and form as the agency may prescribe by regulation and shall demonstrate to the satisfaction of the agency—

(1) that the research entity has established an institutional animal studies committee (hereinafter in this section referred to as the "committee") composed of not fewer than three members who collectively possess sufficient expertise to assess the appropriateness of animal use in experimental research and of which—

(A) at least one member is a doctor of veterinary medicine;

(B) at least one member is not affiliated with the research entity or parent organization and is primarily responsible for representing community concerns regarding the welfare of the animal subjects; and

(C) not more than three members are from the same administrative unit of the research entity;

(2)(A) that such committee—

(i) will meet regularly, and will have an appropriately constituted quorum for all formal actions;

(ii) will make inspections at least semiannually of all animal study areas and facilities of such research entity;

(iii) will review, as part of the inspection, research methods and practices in progress involving direct use of conscious animals, and the condition of research animals, for the purpose of evaluating these research methods and practices to ensure that animal pain and distress are minimized, and for compliance with experimental design of the original approved proposal, or with accepted standards for appropriate animal care, treatment, and use; and

(iv) will file with the responsible Federal agency certification that such inspections and reviews have taken place, along with reports of any violations of assurances given pursuant to this section, deficient conditions of animal care, treatment, or use, or deviations of research methods and practices from originally approved proposals in a manner adversely affecting animal welfare; and

(B) that such inspection certification will be signed by a majority of the members of the committee, and that minority views shall be included in the reports if any members so desire, except that, if either of the members designated in paragraph (1)(A) or (B) of this subsection do not sign the majority report, they shall be particularly notified of the opportunity to file a minority report and given a reasonable time to do so;

(3) that the committee will maintain complete records of their inspection visits (including attendance of committee members), and other information pertinent to its activities, and that such records will be maintained for at least three years and will be available for inspection by any authorized Federal agency;

(4) that members of the committee will be encouraged individually to notify in writing the Animal and

Plant Health Inspection Service of the Department of Agriculture, the responsible Federal agency, and the applicable accrediting agency (under section 202) of any unacceptable conditions of animal care, treatment, or use which have not been reported in writing by the committee as a whole and which have persisted despite notification to the research entity; and

(5) that the committee will establish courses or sessions available annually for scientists, animal technicians, and other personnel involved with animal care, treatment, and use by the research entity, which provide instruction or training in (A) the humane practice of animal maintenance and experimentation, and (B) the concept, availability and use of research or testing methods that minimize the use of animals or limit animal distress.

(b) In those cases where the sponsoring Federal agency determines that conditions of animal care, treatment, or use in a particular project have been persistently unacceptable despite notification to the research entity, that agency shall suspend or revoke Federal support for the project.

(c) Research entities shall inform their employees of the provisions of this title and shall instruct such employees to report to the animal studies committee any violations of such provisions, and no employees of such entities shall be dis-

criminated against in their employment because such employees reported any such violation.

(d) The Secretary may waive the accreditation requirements under exceptional circumstances related to the needs for research results or special and unusual circumstances of the research entity.

COORDINATION

SEC. 204. The Secretary shall facilitate agency compliance with the requirements of this title through the establishment of a clearinghouse for information regarding appropriate methods and research models which are in compliance with such requirement.

DEFINITIONS

SEC. 205. For purposes of this title—

(1) the term "Federal agency" means an executive agency as such term is defined in section 105 of title 5, United States Code, and the term "responsible Federal agency" with respect to any research entity means the agency from which the research entity has received or may receive a Federal award for the conduct of research, experimentation, or testing, involving the use of animals;

(2) the term "Federal award for the conduct of research, experimentation, or testing, involving the use of animals" means any mechanism (grant, contract, cooperative agreement, or loan) under which Federal funds are provided to support the conduct of such research;

(3) the term "animal" refers to any living warm-blooded animal, that is, birds and mammals;

(4) the term "research entity" means any school (except an elementary or secondary school), institution, organization, or person that uses or intends to use live animals in research, tests, or experiments, and that is eligible to receive funds under a grant, cooperative agreement, loan, or contract from a Federal agency for the purpose of carrying out research, tests, or experiments on those animals;

(5) "direct use of conscious animals" means any use that involves more than momentary minor pain or discomfort, or any procedure except where the animal is anesthetized throughout the entire course of that procedure; and

(6) the term "large numbers of animals" means more than one hundred animals for rodent species, more than ten animals for nonrodent species, and one or more for nonhuman primates.

EFFECTIVE DATE

SEC. 206. The provisions of this title shall apply to any research entity that receives an award for the conduct of re-

search, experimentation, or testing, involving the use of animals approved by any Federal agency on or after a date which is three years after the date of enactment of this Act, except that regulations implementing this title may be issued prior to that date.

TITLE III—SPECIAL PROCEDURES

FEDERAL AGENCY REVIEW OF AWARD PROPOSALS

SEC. 301. No Federal agency shall, after the effective date of this title, approve any research entity for the receipt of a Federal award for the conduct of research, experimentation, or testing, involving the direct use of conscious animals, unless the agency finds, as a result of its review of the scientific merit of the proposal, that the award proposal—

(1) includes a justification for anticipated animal distress in terms of the benefits of the research;

(2) includes, in any case involving the direct use of conscious animals, appropriate assurances that the services of a consulting doctor of veterinary medicine have been employed in the planning of such procedures;

(3) includes, in any case involving the direct use of conscious animals, appropriate provisions for assurances of the proper use of tranquilizers, analgesics, anesthetics, and paralytics, and for appropriate pre- and postsurgical medical and nursing care; and appropriate

assurances that the withholding of tranquilizers, anesthesia, analgesia, or euthanasia when scientifically necessary shall continue for only the necessary period of time; and

(4) includes, except in cases of scientific necessity or other special circumstances as determined by the animal studies committee, assurances that no animal shall be used in more than one major operative procedure from which it is allowed to recover.

DEFINITIONS

SEC. 302. For the purposes of this title the terms "Federal agency", "responsible Federal agency", "research entity", "Federal award for the conduct of research, experimentation, or testing, involving the use of animals", "direct use of conscious animals", and "animals" have the meanings provided under section 205.

EFFECTIVE DATE

SEC. 303. The provisions of this title shall take effect one year after the date of enactment of this Act.

SEC. 304. No regulation promulgated under this Act shall take effect if disapproved by either House of Congress within sixty days of its proposal.

TITLE IV—EXEMPTION

SEC. 401. (a) Nothing in this Act shall be construed to apply to research, experimentation, or testing intended to im-

prove animal nutrition, health, breeding, management, or production efficiency in horses, livestock, or poultry used or intended for use as food, including fish, or fiber, or for improving the quality or safety of food or fiber. Nothing in this Act shall be construed to apply to research, experimentation, or testing intended to improve wild animal conservation, propagation, or management.

(b) Nothing in this Act shall be construed to apply to specific experiments, research programs, or research facilities for which the accreditation, assurances, and award requirements of section 201, 202, 203, and 301 of this Act would present specific risks to national security or the safety of manned space flight. Such exemption shall be effective upon certification by the responsible agency head to the Secretary that such risks are involved, along with reasons and justification. All such exemptions must be recertified annually and be available in an unclassified form for public review.

TITLE V

SEC. 501. All authority conferred by this Act shall terminate ten years after enactment.

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON D.C. 20201

SEP 21 1982

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

There is now pending before your Committee H.R. 6928, a bill "To promote the development of nonanimal methods of research, experimentation, and testing, and to assure humane care of animals used in scientific research, experimentation, and testing." H.R. 6928, as reported by the Committee on Science and Technology, is a revised version of H.R. 6245, on which you requested a report.

The bill would authorize the Secretary of Health and Human Services to support development and validation of methods of research, experimentation, and testing that do not require the destruction of live animals, and create an Advisory Panel to the Secretary to make recommendations and to assure appropriate review. It would also require Federal agencies to conduct or support research, experimentation, or testing with animals only in accredited facilities which have established institutional animal studies committees. Finally, the provisions of this bill would allow Federal agencies to approve awards for animal research, experimentation, and testing only when proposals have included specific justifications and assurances relevant to the use of animals.

In summary, we strongly support the objectives of H.R. 6928, the humane and appropriate use of live animals in research and testing protocols. However, we oppose the bill because many provisions are being implemented administratively under existing authorities, and because other provisions create regulatory, administrative, and financial burdens which seem certain to encumber health research severely without a commensurate gain in the well-being of laboratory animals.

The following are specific comments on particular provisions of the bill:

Title I

Title I would authorize the Secretary to sponsor the development of nonanimal methods of research, experimentation, and testing. This authority is not needed. Under the provisions of the Public Health Service Act, the Secretary already is authorized to conduct and support research related to the cause, prevention, and treatment of disease, including the development of nonanimal models of disease processes and of substitutes for animals in biological testing. The Department of Health and Human Services (HHS) has a

well-established program for the development of nonanimal methods--the National Toxicology Program (NTP), a multi-agency effort directed by the National Institute of Environmental Health Sciences of the National Institutes of Health (NIH). The NTP develops and evaluates new biological testing methods which either eliminate the need for animals or reduce the numbers of animals required to test for carcinogenicity, mutagenicity, and other toxic effects. The NTP also disseminates information about toxicological test results and new or improved testing methods to Federal research and regulatory agencies and to the scientific and technical community at large so that these methods can be adopted in a timely and effective manner.

Title I would also authorize the Secretary to designate an Advisory Panel to design a system to assure that applications approved by peer review groups but as yet unfunded are considered by all appropriate programs of this Department. Again, there is sufficient authority in current law and in administrative practice. The application receipt and referral system at the NIH Division of Research Grants already functions well in this capacity, and mechanisms for any desired expansion of the referral system already exist.

Title II

Title II would require facilities using research animals to be accredited and monitored by an organization designated by the Secretary and would require facilities to establish institutional animal studies committees. If Federal Government support is used to meet these requirements, funds would have to be diverted from other important research activities. We believe this issue deserves extensive additional study before any legislation is enacted.

A number of the specific requirements in Title II concerning institutional animal studies committees are unnecessary because the Department is already implementing similar procedures in a way that is likely to be far less costly. For example, in accordance with Public Health Service recommendations and guidelines, essentially all institutions with HHS-funded animal research and testing programs have already established animal studies committees to review animal facilities and practices and to assess compliance with the NIH Guide for the Care and Use of Laboratory Animals; the vast majority of these committees have veterinarians as members, and many also have lay members. Revised instructions which will be issued soon will require not only that at least one member of each committee be a veterinarian, but also that committees have public members as well. Furthermore, the bill would require each animal studies committee to file two reports a year on every relevant project. The paperwork resulting from this excessive Federal regulation would be so extensive as to make review expensive, time-consuming, and wasteful of limited resources, and would not necessarily further the goals of the bill.

With regard to oversight of animal research, a number of activities are ongoing. Inspections of animal facilities and laboratories supported by the Food and Drug Administration are made periodically by that agency in order to assure compliance with Good Laboratory Practices guidelines. The Animal and Plant Health Inspection Service of the Department of Agriculture also conducts

inspections as part of its administration of the Animal Welfare Act. A Memorandum of Understanding and Agreement being developed between this department and the Department of Agriculture should enhance coordination and communication. Although NIH does not carry out routine inspections of animal facilities, it does make such visits when circumstances warrant. In addition, NIH is initiating an expanded program of random site visits to animal facilities at NIH-funded institutions.

Title III

Title III would unnecessarily specify information to be included in research and development proposals which involve the use of animals. Again, current practice satisfies this requirement. The Public Health Service Grants Administration Manual requires that institutions assure NIH, in writing, of their commitment to follow the Guide for the Care and Use of Laboratory Animals. Furthermore, Public Health Service guidelines for members and executive secretaries of initial review groups make clear the responsibilities of those groups to ascertain and assure proper care and use of animals. Under recently refined NIH guidelines, for example, review panels are required to address explicitly the appropriateness of the choice of species and the number of animals to be used, in any protocol where vertebrate animals are specified. Review groups must also address the justification for using animals, in terms of the likely results of the research, and judge whether animals will receive proper care and maintenance. Finally, the reviewers must determine that the animals will not suffer unnecessary discomfort, pain, or injury. Applications may be deferred, disapproved, or approved with restrictions in any case where reviewers question the appropriate use of animals.

In conclusion, we believe that current statutory authorities and administrative practices are sufficent to ensure humane treatment and care, and appropriate use, of animals in research and testing and to foster the development of accurate and suitable nonanimal methods in these areas.

We therefore recommend that the bill not be favorably considered.

We are advised by the Office of Management and Budget that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

Secretary

Mr. WAXMAN. Thank you, Mr. Walgren. Let me commend you for the hard work you have put into this issue. I know you have worked many hours on this question in your own Subcommittee on Science Research and Technology and that you have taken into consideration so many of the different issues that are subliminal to the major question and worked hard to resolve those issues. It is a commendation to you that this bill passed your own subcommittee unanimously.

Senator Melcher, we are pleased now to have the opportunity to review this legislation with you and welcome you to the subcommittee. I am sorry that we delayed your schedule and I know you must get over to the Senate to work on the many issues that remain for the last week or two of this session. I know you are a veterinarian and, therefore, have a strong interest in the proper treatment of animals and we are anxious to hear from you about this.

STATEMENT OF HON. JOHN MELCHER, A U.S. SENATOR FROM THE STATE OF MONTANA

Senator MELCHER. Thank you very much, Mr. Chairman and members of the committee and the subcommittee. I do not know whether you are a member of the subcommittee or not, Pat.

I am delighted to be here this morning and do not be afraid that my schedule is such that we do not have time to discuss this matter. I think you are on to a real important subject here.

First of all, I would like to say that I believe there is a Federal responsibility involved that we cannot ignore. It is always a question in times of budget constraints of whether or not we can engage in any type of legislation that possibly would lead to a broader participation of Federal funds. I want to assure all of you that it is my strong feeling that we do have that Federal responsibility and that we cannot ignore it. I am delighted that the subcommittee and the full committee has resisted massive cuts in health research—one of the things that seems to be easiest always to cut.

We have an obligation to place before the public the need for the continuation of health research, and it varies across a broad spectrum. If we avoid that responsibility, we are not saving anybody. We are causing added costs to be borne by citizens of this country later on for lack of the timely health research that must be carried on continuously.

As to the second point of means to avoid killing or harming animals in carrying out the research, surely all of us agree on that. I think we have to be realistic about it. I am personally biased to the continuous over research use of rats and mice and guinea pigs. I think all too often some of the results are not reliable because I do not know how reliable an inbred strain of mice or an inbred strain of rats are in taking those results and then trying to apply them to what happens in a human being.

That is a personal bias that I have, but I think there is some practical means of avoiding that type of heavy reliance on using those types of research animals. Now if there are better means available, the best, of course, would be to use humans. After all, our environments as human beings are extremely different than

inbred rats, mice or guinea pigs in a laboratory. But, unfortunately, we do not find too many human beings wanting to be used as experimental animals.

I had a job once when I first attended college in a laboratory at the University of Minnesota, and my job was, I think, 50 cents an hour and it was manual labor. So when I became aware that there was going to be a job that paid 60 cents an hour to test thermal underwear at various degrees of cold temperatures I was strongly interested. First of all, it would be easier and, second, it would be 10 cents an hour more.

I do not remember the results of those tests. They were supposed to lower the temperature to either shivering or at least to show a few goose bumps. That is the kind of experimentation that can be accomplished with human beings, but unfortunately there is not much else that can be. So most of our basic research is done with laboratory animals.

But I think we can do a better job. If we can do a better job and I think we can; I think there are opportunities to do a better job without using laboratory animals then we certainly ought to encourage it.

For a number of years I have been watching the development of the animal welfare legislation, including the current Animal Welfare Act enforced by the Department of Agriculture. I was on the Agriculture Committee here in the House when we considered aspects of that or amendments to that act I think you were on it too, were you not, Ed? We had strong hopes that we were going to see great improvement in the care of laboratory animals, and there has been some improvement.

But over the course of the past several years I wanted to see what the Department of Agriculture was able to accomplish in implementing that act, in better inspection and enforcement of laboratory animal care. But it required putting money where our mouth is. I have recently concluded that the administration and Congress is not going to allocate the reasonable funds to enforce this act, the Animal Welfare Act and I approached the thought that reasonable enforcement is probably not feasible under the circumstances.

If that is the case, then it seems to me it is time to find an effective way of assuring that those laboratories that are receiving Federal funds are providing the best possible care for their laboratory animals.

I have also been concerned, as I watched the various proposals develop, to stimulate the use of alternate methods and resources in an effort to limit the need for using live animals in research and testing. I am wholeheartedly in support of this basic idea. But while I am anxious to stimulate faster development of alternative methods than at present, I realize that is easier said than done.

As I understand it, most of the good alternatives have developed as an added benefit of an existing research program. Certainly the cost of laboratory animals, the cost of keeping them, and the problems of working with them are all stimulants to the development of alternatives. But more needs to be done.

I have cosponsored with Senator Dole S. 2948 and the amendment to that bill, which is, I believe, 3020, introduced in the

Senate, and I strongly believe there is need for this additional stimulus which is embodied in the bill and in the amendment, and which you have talked about this morning, Doug, and embodied, surely, in the bill before the House.

I believe this would be progress and it is needed. We can do it. I doubt that anyone really knows the cost to research institutions of rapidly coming into compliance with the NIH guidelines or to be accredited by the American Association for the Accreditation of Laboratory Animal Care.

Now a careful study of that cost should be undertaken, and that is exactly what this amendment I spoke of, Senator Dole's, does. That amendment also provides for the implementation of specific standards using the judgment developed in the study in such a way that accreditation requirements would not hamper any research entity's ability to comply. It seems to me that that provides a reasonable way of adding an appropriate stimulus to improve laboratory animal care.

Another matter concerns me, however, and that is the ultimate responsibility for the improvement of facilities over the next decade or so. I think we need the results of this study proposed by Senator Dole's amendment so that we can make a realistic judgment of those costs. I doubt that the entire responsibility for those facilities will be improved, and other improvements can be expected to be borne by the academic and research community alone.

While those decisions have to be made with current facts at hand, I believe we must be willing to consider sharing those costs if we seriously intend to improve the care and treatment of the animals that are so vital to biomedical research.

So I return to my first conclusion. There is a Federal responsibility first to assure that the research continues and, second, that we pay part of the cost of the laboratory testing.

Mr. Chairman, I would like to bring to the attention of all of you that the executive board of the American Veterinary Medical Association supports the concept of S. 2948 and, therefore, the concept of your House bill, and supports it on the condition that this amendment by Senator Dole for the 1 year study to determine the costs and responsibility before regulations are issued by the Secretary becomes part of the bill.

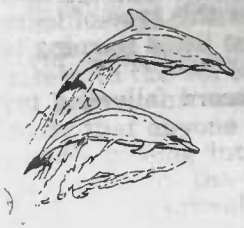
I have noted that a group, Monitor, the Conservation, Environmental and Animal Welfare Consortium has written to me and possibly to the subcommittee also in a letter dated December 3, that the undersigned groups wish to express appreciation of support for this type of legislation and point out that two groups called United Action for Animals and Committee for Humane Legislation, Inc., have disseminated misleading and untrue statements about the bill.

These groups involved with Monitor are the Society for Animal Protective Legislation, American Humane Association, the Washington Humane Society, the Massachusetts Society for the Prevention of Cruelty to Animals, Humane Society of the United States, the Fund for Animals, American Society for the Prevention of Cruelty to Animals, Scientists Group for Reform of Animal Experimentation.

These groups are in a consortium called Monitor, and they want to make it abundantly clear that they do support this type of legislation, notwithstanding the other two groups first listed seeming to be in opposition to it.

I would like to submit that as part of the record following my testimony, if that is appropriate.

[The letter referred to follows:]



MONITOR
THE CONSERVATION, ENVIRONMENTAL
AND ANIMAL WELFARE CONSORTIUM

1506 19th St., N.W.
Washington, D.C. 20036
(202) 234-6576

Decmeber 3, 1982

Dear Co-Sponsor of S. 2948:

The undersigned groups wish to express appreciation of your support for the important bill, S. 2948, to minimize pain and distress undergone by laboratory animals and to develop nonanimal methods of testing and research.

Recently, two groups, "United Action for Animals" and "Committee for Humane Legislation, Inc." have disseminated misleading and untrue statements about the bill. After hearings were held in October, 1981, these groups took no action in the extensive work of the Congress and interested organizations in drafting legislation to prevent needless animal suffering and to encourage development and use of alternative methodology. Instead they are impugning the motives of outstandingly humane Members of Congress in an attempt to kill a bill which offers protection to laboratory animals, earnestly desired by the American public.

UAA and CHL espoused a bill aimed entirely at alternative methods. It contained no provisions for limiting pain and distress. It called for a "set-aside" of 30-50% of National Institutes of Health funds for biomedical research and exclusive use of these funds for development of nonanimal methods.

Although S. 2948 authorizes no new funds, it directs the National Toxicology Program to use its very substantial funding to, in the words of the bill, "significantly increase its resources for research and development on new methodologies and validation of nonanimal research and testing methods or computer models, which could be more rapid, less expensive, equally or more reliable, and generate more useful toxicological and safety information."

S. 2948 represents an immensely valuable legislative means of reducing animal suffering without increasing government expenditures but, in the long term, reducing them through the encouragement of nonanimal testing methods.

Should you or your staff desire further information on the bill and the erroneous charges made against it, you are invited to call the numbers listed on this letter.

Hearings on the companion bill in the House, H. R. 6928, are scheduled for December 9th in the Subcommittee on Health and the Environment, chaired by Representative Henry Waxman. H. R. 6928 has already cleared the House Science and Technology Committee.

Again, thanks for your much valued co-sponsorship of the urgently needed S. 2948. We hope it will soon be law.

Sincerely,

CRAIG VAN NOTE

Craig Van Note
Executvie Vice President

Society for Animal Protective Legislation (337-2332)
American Humane Association
Washington Humane Society
The Massachusetts Society for the Prevention of Cruelty to Animals
The Humane Society of the United States (452-1100)
The Fund for Animals
American Society for the Prevention of Cruelty to Animals
Scientists Group for Reform of Animal Experimentation

Mr. WAXMAN. Without objection, that will be done.

Senator Melcher, let me thank you for a thoughtful statement. It will certainly be most helpful to us to review your comments and the attached items that will be part of the record for this hearing.

Senator MELCHER. Thank you very much.

Mr. WAXMAN. Before I call on Senator Dole, does any member of the subcommittee have any questions?

[No response.]

Mr. WAXMAN. Thank you very much for being here and for your assistance.

Senator Dole, we want to welcome you to our subcommittee. We are pleased to have you with us and the benefit of your comments on this legislation since you have taken an active role on the Senate side.

STATEMENT OF HON. ROBERT DOLE, A U.S. SENATOR FROM THE STATE OF KANSAS

Senator DOLE. Thank you very much, Mr. Chairman.

You have just heard the expert, Senator Melcher. I would first like to associate myself with the remarks of Senator Melcher, who certainly is on our side, and who understands this area better than any other Senator.

I have a statement which I will ask to be made part of the record. But I am here primarily to indicate that there is strong support for this legislation and we hope it would receive further attention this year. That may not be possible. The Senate leader, Senator Baker, is waiting for me to bring him a public utilities bill

right now that does affect the State of California. So you will understand my brevity.

Mr. WAXMAN. We do not want to delay you.

Senator DOLE. Well, we are in that stage of the Congress where everybody would like to just get one more thing done. It would seem to me this is not particularly controversial with my amendment that has just been referred to.

For a long time, perhaps not as long as John Melcher and probably others on this committee, I have had an interest in the reasonable treatment of animals. My mentor was Hyde Murray and Mrs. Stevens. In fact, they worked together very effectively and so I took an interest in an area that I had not really focused on. I think that is probably true of most of us in Congress. We are so busy focusing on so many other things that sometimes we forget about matters that are really important to a lot of people and, in this case, to animals who cannot express themselves as some of us do from time to time.

But almost everybody agrees that humane treatment of animals is a noble aim and it certainly is a responsibility we all have. Some have advocated rather drastic changes; some have advocated no change. I think there are probably areas of agreement between those who have differing views.

The legislation that Senator Melcher has referred to, S. 2948, is not major in the sense that it is going to drastically change the status quo, but it does address a couple of basic areas such as how we can reduce the number of animals used, produce less pain, and how we can avoid or perhaps find some alternatives to using live animals in experiments.

As far as cost is concerned, I understand that there is one indication that the cost might be as high as $500 million. This study certainly, as any study, can be debated. We hope to take care of that with my amendment, S. 3630, and we provide that if in fact the costs are too high the Secretary would be permitted to waive accreditation regulations.

So I would like to say that I am very pleased to have this opportunity to address your committee this morning, Mr. Chairman. We think that accreditation standards and alternatives methods as outlined in the Senate proposal have a great deal of bipartisan support and if there can be some agreement, we in the Senate would be very pleased to try to act as quickly as the House would act. Perhaps even yet this year; if not, perhaps we could start early next year.

But we do need a realistic and uniform set of standards for the care of animals. This may be a small step in that direction, and I appreciate very much this opportunity to indicate that.

I would like to include, following my statement, a summary of the Humane Care and Development of Substitutes in Research Act, and a title by title analysis of the bill.

[Senator Dole's prepared statement and attached summary follow:]

STATEMENT BY SENATOR BOB DOLE
BEFORE THE HOUSE SUBCOMMITTEE
ON HEALTH AND THE ENVIRONMENT

I WOULD LIKE TO BRIEFLY ADDRESS THE "HUMANE CARE AND DEVELOPMENT OF SUBSTITUTES FOR ANIMALS IN RESEARCH ACT AND THANK CONGRESSMAN WAXMAN FOR SCHEDULING THIS MORNING'S SESSION. THIS GIVES US AN IMPORTANT OPPORTUNITY TO ADDRESS A PROBLEM THAT HAS BEEN ATTRACTING CONSIDERABLE ATTENTION THE PAST YEAR.

MOST EVERYONE FEELS THAT HUMANE TREATMENT OF ANIMALS IS A NOBLE AIM AND A NECESSARY RESPONSIBILITY. SOME HAVE ADVOCATED DRASTIC CHANGE AND SOME NO CHANGE. I BELIEVE THAT BOTH SIDES ARE IN AGREEMENT ON SEVERAL POINTS AND PERHAPS WE CAN SATISFY THE CONCERNS OF THE INTERESTED PARTIES FOLLOWING THIS HEARING.

I HAVE INTRODUCED LEGISLATION IN THE SENATE, S. 2948, AND WOULD LIKE TO DISCUSS TWO PROVISIONS OF THAT BILL, ACCREDITATION AND ALTERNATIVE METHODS.

ACCREDITATION

AS AMENDED, S. 2948 WOULD HAVE THE SECRETARY OF HEALTH AND HUMAN SERVICES CONDUCT A STUDY, OF NOT MORE THAN ONE YEAR, TO DETERMINE THE ECONOMIC IMPACT OF MANDATORY ACCREDITATION ON RESEARCH LABS. FOLLOWING THE STUDY, THE SECRETARY WILL ISSUE REGULATIONS FOR IMPLEMENTING THE LOWEST COST PHASES OF ACCREDITATION AND WOULD

ESTABLISH GOALS AND PROCEDURES FOR IMPLEMENTING THE HIGHER COST ASPECTS OF ACCREDITATION SUCH AS MAJOR STRUCTURAL CHANGES.

IF THE SECRETARY DETERMINES THAT ACCREDITATION COSTS ARE TOO HIGH, HE CAN WAIVE THE REGULATIONS. THIS AMENDMENT SHOULD SATISFY THE CONCERNS OF THOSE WHO FEEL THAT COSTS OF ACCREDITATION WOULD BE TOO HIGH. YET IT ENSURES THAT PROPER AND REASONABLE STEPS WILL BE TAKEN TOWARDS ACCREDITATION.

ALTERNATIVES

ONE OF THE OBJECTIVES OF LABORATORY ANIMAL RESEARCH LEGISLATION BEING CONSIDERED BY BOTH THE HOUSE AND SENATE IS TO REDUCE THE NUMBER OF LAB ANIMALS USED IN RESEARCH TESTING.

MANY REALIZE THE IMPORTANT ROLE ANIMAL RESEARCH HAS HAD OVER THE YEARS IN IMPROVING OUR HEALTH AND STANDARD OF LIVING. THE DISCOVERY OF INSULIN AND THE DEVELOPMENT OF CORONARY BYPASS SURGICAL TECHNIQUES ARE TWO EXAMPLES. HOWEVER, ALTERNATIVE METHODS HAVE ALSO YIELDED MAJOR BREAKTHROUGHS SUCH AS THE AMES TEST, NOW USED IN 2,000 LABORATORIES. ANOTHER EXAMPLE WAS A CHEMICAL COMMONLY USED AS A PERSERVATIVE IN SAUSAGE IN JAPAN WAS FOUND TO BE CARCINOGENIC WHEN TESTED WITH ALTERNATIVE METHODS ALTHOUGH INITIAL TESTING WITH RODENTS HAD NOT REVEALED THAT DANGER. SO I'M SUGGESTING IT IS IN EVERYONE'S BEST INTEREST TO TAKE A MORE ORGANIZED APPROACH IN LOOKING FOR ALTERNATIVES, RATHER THAN HAVING ALTERNATIVE METHODS DEVELOP ON A RANDOM BASIS AS A SPINOFF OF OTHER RESEARCH PROJECTS.

THOSE INVOLVED IN SCIENTIFIC RESEARCH WOULD PROBABLY AGREE THAT IT COSTS A LOT OF MONEY TO BREED, HOUSE AND CARE FOR ANIMALS - NOT TO MENTION THE COSTS OF FACILITIES AND TRAINED LABOR. FROM AN ECONOMIC STANDPOINT THEN, ALTERNATIVE METHODS COULD PROVE TO BE A VERY COST-EFFECTIVE INVESTMENT. AS CHAIRMAN OF THE SENATE FINANCE COMMITTEE, I CAN TESTIFY THAT TAXPAYERS LIKE COST-EFFECTIVE GOVERNMENT PROGRAMS. I REALIZE THE IMPORTANCE OF GAINING SCIENTIFIC KNOWLEDGE TO BETTER CURE, TREAT AND UNDERSTAND HUMAN DISEASES. AND I UNDERSTAND THAT MUCH OF THE RESEARCH AND TESTING INVOLVING ANIMALS SIMPLY CAN'T BE REPLACED BY COMPUTER MODELS AND TISSUE AND CELL CULTURES. HOWEVER, TO THE EXTENT FEASIBLE AND PRACTICABLE, WE SHOULD CONSIDER USING ALTERNATIVES AND TAKING AN ORGANIZED APPROACH TOWARDS THEIR DEVELOPMENT.

CONCLUSION

IN CONCLUSION, I REPEAT THAT ALL THOSE INVOLVED IN THIS DEBATE MAY NOT BE FAR APART. BOTH SIDES OPPOSE UNPRODUCTIVE EXPERIMENTS AND NEEDLESS SUFFERING AND BOTH FAVOR DEVELOPING ALTERNATIVE METHODOLOGIES WHEREVER POSSIBLE. NO ONE SHOULD WANT TO IMPEDE SCIENTIFIC PROGRESS OR SACRIFICE THE DEVELOPMENT OF NEW MEDICINES NEEDED FOR HUMANS. LET'S JUST BE CERTAIN AS WE CAN, THAT WE HAVE A REALISTIC AND UNIFORM SET OF STANDARDS FOR THE CARE OF ANIMALS.

SUMMARY OF HUMANE CARE AND DEVELOPMENT OF

SUBSTITUTES IN RESEARCH ACT

TITLE I

The Secretary of Health and Human Services (HHS) is authorized to make awards to sponsor research into methods that 1) do not use live animals, 2) reduces the number of animals used or produces less pain.

An advisory panel will ensure every consideration will be given to such programs for funding and they will advise the Secretary of his responsibilities in this area.

The Secretary will direct the National Toxicology Program to significantly increase its resources for R&D on new methods and validation of nonanimal research testing.

TITLE II

As amended, would require the Secretary of Health and Human Services to conduct a study of the impact mandatory accreditation would have on research facilities. Following the study, the Secretary would issue mandatory regulations to implement the lowest cost procedures toward accreditation and would establish goals and procedures for implementing the higher cost aspects of accreditation such as structural changes. If costs are determined to be too high, the Secretary will waive accreditation regulations.

Research entities must maintain an animal studies committee which includes a veterinarian and a nonmember of the entity. The committee will make semiannual inspections of the facilities to review research.

TITLE III

Establishes certain procedures that peer reviewers must look for in research proposals involving the direct use of conscious animals.

TITLE IV

Exempts animals used for food production.

TITLE V

Sunsets after 10 years unless reenacted.

Mr. WAXMAN. Thank you very much, Senator Dole. Without objection, your full statement and the additions to it will be made part of the record.

I appreciate your interest in this issue and your assistance in giving us the benefit of your recommendations with Senator Melcher.

Let me ask both of you. This bill has already gone through the House Science and Technology Committee and is now in a subcommittee of the Energy and Commerce Committee. I gather on the Senate side a bill like this would either go to the Agriculture Committee or to the Labor and Human Resources Committee. Do you know whether either of those committees has considered the legislation over there?

Senator DOLE. It has not been considered, but we have considered things rather quickly at times.

Senator MELCHER. I have drawn the attention of Senator Hatch, chairman of the Labor and Human Resources Committee, to the bill and to the amendment and encouraged him to become familiar with it.

Senator DOLE. If there was some indication that it might be moving in the House, I really believe that we could have hearings yet, like next week, if we can prevail on Senator Hatch. I believe it has primary jurisdiction in the Labor and Human Resources Committee.

Mr. WAXMAN. I think you have expressed the feeling of all of us that we would like to do something responsible in this area because conditions which allow inhumane treatment of animals cannot be tolerated. I would like to work with the two of you and, of course, Congressman Walgren and others to see if we can accomplish that result.

If we can do it this year, that would be the best result. If we cannot, then we must continue to work on this issue so we can accomplish what is necessary in the public interest through legislation.

Mr. Madigan.

Mr. MADIGAN. Senator, will this utility bill help the people in the Los Angeles Basin?

Senator DOLE. I understand it is widespread. Generally, when we do anything in the Senate we help everyone. That is part of our problem.

It is very important to the Los Angeles Basin, yes.

Mr. MADIGAN. Well, we sure want you to be able to get back there to take care of it, then.

Senator DOLE. It also shortens the holding period, but that is another matter. Thank you very much.

Mr. WAXMAN. Thank you very much.

Mr. DANNEMEYER. I have a question, Mr. Chairman.

I am just curious about the observations of our two distinguished Senators present as to what is the failing of the existing Animal Welfare Act dealing with treatment for animals, protecting them ostensibly, under the jurisdiction of the Department of Agriculture that you feel needs addressing by the enactment of the proposed legislation which, as I see it, would put another agency of the Fed-

eral Government into the same regulatory mold that the Department of Agriculture is now doing.

Are you familiar with this letter from Secretary Block of the Department of Agriculture to our esteemed colleague, Mr. Walgren, dated May 13, 1982?

Senator DOLE. I think I have looked at it, yes. I have not looked at it lately. I doubt if Block looked at it, to be very honest.

Mr. DANNEMEYER. The third page is signed by John R. Block, or what appears to be John R. Block, and he objects to the bill on the ground that it is turf fighting, and that may be an oversimplification on my part to assert that this is nothing more than a turf fight between Agriculture and HHS.

But if there is a law today that addresses this concern, I would like to have your observations as to how the existing law is deficient so that we have to enact a new law to get a new agency perhaps involved in administering or doing the same thing.

Senator MELCHER. I can express my personal feeling, but I can also say that it is not mine alone. We have watched the funding to carry out the duties under the Animal Welfare Act and have found that, first of all, the budgets, as proposed, do not carry enough money, because, after all, if you are going to make the inspections, that does cost money, to send the people out from the Department of Agriculture to make those inspections and then get them back there to enforce the cleanup that is necessary as a result of the inspection. By "cleanup" I mean corrections, whatever they may be.

These types of inspections are the type of inspection where you have to tell somebody with laboratory animals that they are not following the regulation, and they are not popular inspections with the laboratories that are receiving the inspections, nor are they popular with those employees of the Department that must come in and prove themselves, and tell them that they have got to correct it without sufficient funds.

That has been the case over the past several years. There simply has not been enough inspection. That can be corrected. Let me hasten to add that. But it does depend on both the administration and Congress providing sufficient funds for it. You know, it tends to be sort of a low priority item in the Department of Agriculture's budget and tends to be a low priority with Congress.

But this bill really offers an opportunity in working with the research laboratories. Isn't there some way of doing it better? And I do not know that it is going to add much to the cost. I think the amendment we spoke of of Senator Dole's for this 1-year study to make sure what the costs are is significant because I think with that sort of guidance can we do a better job with the same amount of money and decrease of pain or decrease in number of animals that actually have to be used is commonsense.

So I think what we are doing here in this proposed bill is heading in that direction and I do not think that is much of a turf fight, really, because, after all, the Secretary doles out the money, excuse me, Bob. The Secretary approves these grants for research and has to be the one to make the determination of whether or not it could be done in a different way. That does not really infringe on the Department of Agriculture at all.

It goes in the way, I think, that sensible people in the Department of Agriculture and, I assure you, I think Secretary Block would agree with that aspect of it, that if we can get away from animals or if we can cause less pain, let's do it.

Senator DOLE. Could I just add that there is an analysis of the difference between the Animal Welfare Act and the House bill. I understand that a later witness will submit the analysis for the record because there are a number of differences.

[The document referred to follows:]

COMPARISON OF H.R. 6928 AND THE ANIMAL WELFARE ACT (as it relates to lab animals)

H.R. 6928	ANIMAL WELFARE ACT
Alternatives	
• Authorizes the Secretary of Health and Human Services to make awards to sponsor research into the development and use of methods of research and testing which do not require the use of live animals, which reduce the numbers of live animals used, or which produce less pain and distress • Directs the government to promote within its own agencies the development of new research and testing methods that do not require the use of animals • Establishes an Advisory Panel for coordination of alternatives • Promotes the development and use of alternatives to the current requirements in public safety testing • An Animal Studies Committee must develop and conduct courses on both humane practices and the use of alternatives. • Directs the National Toxicology Program to significantly increase its resources for research and development on nonanimal methods of research and testing	• Silent on alternatives
Registration and Accreditation	
Sets up a rigorous accreditation program, based primarily on the NIH Guide for the Care and Use of Laboratory Animals, for those research entities receiving federal funds.	• Registers research facilities and requires minimum humane handling, care, treatment and transportation standards enforced by USDA on-site visits. This applies to all facilities whether or not they receive federal funding. Also requires registrants to keep records of each purchase or sale of live dogs and cats and to maintain identification tags for every dog and cat.
Research Review	
• Calls for an Institutional Animal Studies Committee which must include at least one member not affiliated with the research entity who represents the animal welfare concerns. This Committee is charged, among other things, with assessing the appropriateness of animal use in experimental research.	• USDA is specifically prohibited from interfering with the design and performance of actual research or experimentation. It is, however, required to determine if proper veterinary care is being provided. Registrants must submit annual reports disclosing species and number of animals used, and showing that pain-relieving drugs were used in experiments deemed to cause pain or distress. Current regulations do not define "pain" or "distress."
Inspections	
• The Animal Studies Committee must meet regularly and conduct at least semi-annual inspections; file findings with funding agencies; establish courses on humane practice and availability and use of alternatives.	• USDA conducts irregular inspections depending on budget and other agency priorities. Silent on other items.
Penalties	
• In those cases where the sponsoring federal agency determines that conditions of animal care, treatment or use in a particular project have been persistently unacceptable despite notification to the research entity, that agency shall suspend or revoke federal support for the project.	• No provision for revoking funding. Violation by a research facility of any provision of the Act is punishable by a fine of up to $1,000. USDA may also impose cease-and-desist order, violation of which is punishable by fines of $500 for each day violation continues.

H.R. 6928	ANIMAL WELFARE ACT
Interagency Communication	
• Establishes a clearinghouse for information to enable federal agencies to coordinate compliance with the requirements of this Act	• USDA has no authority over other federal agencies other than an annual written assurance from each agency that it complies.
Animals Included	
• Animals refers to any living warm-blooded animals, that is, birds and mammals. • Exempts animals used or intended for use as food or fiber	• Regulations do not cover rats, mice or birds. • Same
Conditions for Federal Grants	
• No federal money can be awarded unless the proposal includes: —justification for anticipated animal distress in terms of the research —assurances that a veterinarian has been employed in planning —provisions for assurances of the proper use of tranquilizers, analgesics, anesthetics, and paralytics, and for appropriate pre- and post-surgical medical and nursing care; and appropriate assurances that the withholding of tranquilizers, anesthesia, analgesia, or euthanasia when scientifically necessary shall continue for only the necessary period of time —assurances no animal shall be used in more than one major operative procedure from which it is allowed to recover	• None
Exemptions	
• Exempts research, experimentation, or testing intended to improve wild animal conservation, propagation, or management • Exemptions are possible based on risks to national security or the safety of manned space flights, but the agency must provide justification for public review annually. • Exempts elementary, secondary, and all other schools below the college level	• Sets minimum standards for humane care, treatment, handling, transportation, and housing of animals in zoos, aquariums, circuses, or otherwise on public display • Silent on this • Same

THE HUMANE SOCIETY OF THE UNITED STATES

Mr. WAXMAN. Thank you very much.

Mr. WALGREN. Would the gentleman yield, if I can briefly respond also along the same lines?

We really are moving away from the invasive external inspection and setting up a structure that will build these values in. Therefore, we will not have to rely on the difficult invasion of any Federal inspector but, rather, create somebody in the system in the animal care committee who has internal relationships to encourage these efforts to come up to standard.

There are not any bad guys in this. It is just a question of building in the proper considerations at the proper time so that we do not wind up with some kind of a horror story. I believe you are absolutely right that proper enforcement may be impossible because of the adversary nature. It certainly is not probable, in view of the limiting funding, largely because the inspectors also have responsibility for the care of plants, and other users of animals, and that detracts from the care in the laboratory animal area.

There was testimony before the Science and Technology Committee that we had nationwide about 20 person-years involved in the effort of external inspection, and that is just not enough to assure us, as we deserve to be assured, in my view, that the millions of dollars that are being allocated by the Federal Government are being allocated under the proper circumstance.

I appreciate the gentleman yielding for that much of a comment.

Mr. WAXMAN. Anything further by members of the subcommittee? If not, thank you very much, gentlemen.

I would like to recognize our next two witnesses. First is our colleague, Representative Pat Schroeder, who is a cosponsor of H.R. 6928 and the author of H.R. 4406, which would amend the Animal Welfare Act to insure the humane treatment of laboratory animals.

Second, I would like to call forward Mrs. Lantos, who is representing her husband, even though he is here. Maybe he would like to come forward as well. This is Annette Lantos and Congressman Tom Lantos, both from my own State of California, who have been very involved in this legislation. We would like to welcome both of you.

Mrs. Schroeder, would you like to go first?

STATEMENTS OF THE HON. PATRICIA SCHROEDER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO; HON. TOM LANTOS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA; AND ANNETTE LANTOS ON BEHALF OF HON. TOM LANTOS

Mrs. SCHROEDER. Thank you, Mr. Chairman and members of the committee. I would like to ask consent to put my testimony in the record and just summarize rapidly.

I think you have heard an awful lot about this issue. How did I get into this issue? My children kept pricking my conscience and when you really wonder why they identify with how we as a society treat animals I think it is because they feel vulnerable and identify with other things that they think are vulnerable.

And it even rang bells because I could think back to when I was 3 years old and used to tour the hospital with my uncle, who was a doctor, and see the rabbits and get distressed about how they were being kept. I realized that that was a concern.

I also remember that Ghandi used to say that you test a nation's civilization by how they treat animals and I think that there is an awful lot to be said about that.

What we want to do is make sure we do not have the horror stories. No one is trying to stop research. I think Congressman Walgren's statement that it is not Fido versus you is absolutely correct. That is not what we are trying to do, but it is trying to make sure that you do not have some unconscionable thing going on and that every precaution is taken that is possible and reasonable to make sure that that does not happen.

So basically what this bill does—and I think people have summarized it very well—is that it encourages in-house monitoring. It says this is a focus; this is terribly important. The Federal Government considers this very important. We want this emphasized. Do it in-house. They are not trying to absolutely stop the use of animals in research.

I remind you that the Welfare Act does not cover laboratory animals in many instances. What this is saying is that this committee has to meet regularly—this in-house committee—that it should inspect the facilities at least twice a year, that it should review the animal research projects. Actually, there could be a very significant savings if they find duplication or what have you. And they should look at especially those that cause lots of pain, stress, and suffering to make sure that they are not overdoing those in any way, shape, or form. And they come out with some fairly broad responsibilities.

But, again, it is not the big bad guy from Washington out touring, spending lots of money doing this. Again, it is in-house and trying to do it that way. It requires one member from the community to be in there. I remind you that the institution selects that one person as the liaison to the community, to explain what is going on to groups and to children and to other people who are very concerned about the animals, who explain what all they are doing.

I just think that this is all very, very, very, very, important and it tends to always get pushed to the bottom. And yet I think it is not one of the things that should be pushed to the bottom because we are a civilized society and pride ourselves in our care.

The cost estimates that have been thrown around absolutely amaze me. I have heard people say $65 million. I heard this morning $500 million. I just want to remind people that the human institutional reviews boards, which are terribly important and govern many, many more things in the National Commission for the Protection of Human Subjects only costs $10 million a year, and they do a lot more than what this is projected to do, because this is, again, more in-house.

So I think it is a little outrageous to project that the animal care board is going to cost more than the human studies board, and especially when you look at the structure of it. So what we are doing

is saying that we are just expanding a bit on what the rules already are.

There are some rules already about what happens if you get a Federal grant. This tries to change the focus from being a Washington focus to an in house focus with a little more or much more comprehensive guidelines about what is exactly expected. I think it is terribly reasonable and I would hope that we could move it just as rapidly as possible.

I did not mention title I. I do support title I too. I think it is important that we look at alternatives if at all possible, but I wanted to basically focus on these specific provisions because they are the most similar to the kinds of legislation that I have been pushing in the past and am now cosponsoring here.

So, I again thank you very much for allowing me to be here.

[Mrs. Schroeder's prepared statement follows:]

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STATEMENT OF CONGRESSWOMAN PATRICIA SCHROEDER, (D-COLO),

BEFORE THE HOUSE COMMITTEE ON ENERGY AND COMMERCE

SBUCOMMITTEE ON HEALTH AND THE ENVIRONMENT

DECEMBER 9, 1982

Mr. Chairman and members of the committee, I want to thank you for calling these hearings and giving me the opportunity to testify on this issue.

In both the 96th and the 97th Congress I introduced legislation aimed at reducing the suffering of animals subjected to research and experimentation. Key elements of my legislation have been incorporated into the bill now before this committee -- a bill that I feel deserves swift enactment.

H.R. 6928 has come under fire from many segments of the scientific community who claim it is aimed at eliminating their freedom of inquiry. Nothing could be further from the truth. This legislation is a compromise reached after long hours of work by animal welfare and scientific groups. It strikes the necessary balance between academic freedom and the welfare of animals.

This bill does not prohibit nor even restrict the use of animals in research. It does, however, seek to assure that the animals used are humanely cared for before, during, and after experimentation. While the federal Animal Welfare Act, originally passed in 1966, addressed part of this problem, it does not cover the actual use of laboratory animals. Passage of H.R. 6928

would address these deficiencies and also raise the general standards of laboratory animal care and welfare in the nation's research facilities.

The most important element of this legislation requires the establishment of Animal Studies Committees in each research facility covered under the act. Currently, guidelines issued by the National Institutes of Health (NIH) call for these committees to be established at all research facilities that receive federal funds. Many of these committees, however, have only minimal input into how research animals are treated. Not many more than the top grade research facilities have committees that come close to meeting the standards laid out in this bill. It is vital that the committees meet regularly, that they inspect the facilities at least twice a year, and that they review animal research projects, especially those involving significant animal distress, pain, and suffering. The bill would give these committees broader responsibilities than they now enjoy under the NIH guidelines. Under the provisions of the act, each committee would fulfill the important community liaison role through the requirement that one member of the committee be unaffiliated with the research facility and specifically charged with representing the welfare of animals. The committee would also orchestrate the vital role of training researchers in humane care and in the concept of alternatives. By contrast, the Animal Welfare Act contains no provisions for review of experimental protocol by the local institution, and in fact specifically prohibits the enforcement authority from interfering with the design and performance of actual research or experimentation.

It has been argued by opponents of this legislation that the requirement for the establishment of Animal Studies Committees would cost $65 million a year.

This is a grossly inflated figure. At Colorado State University, in Fort Collins, Colorado, the Biohazards Committee, the Humane Institutional Review Board and the Animal Care Committee (which already fulfils the requirements of this bill with the exception of the non-affiliated member), share a half-time secretary. Human Institutional Review Boards certainly do not cost anywhere near $65 million. Estimates from the National Commission for the Protection of Human Subjects indicate the total cost to be approximately $10 million. There is no reason to expect H.R. 6928's Animal Studies Committees to cost six times the total cost of the Human Institutional Review Boards, especially since most institutions already have committees in place (at least in name).

H.R. 6928 would also help guarantee humane treatment of reseach animals by imposing strict conditions that must be met in order to receive federal funds. These requirements allow a research facility to perform any experiment that he or she can justify as necessary and of reasonable benefit. Anybody applying for a federal grant must already do this. The only change is that animal suffering should be included in the cost-benefit equation. The possible withholding of federal funds will go far towards ensuring humane standards of care. Although the current Animal Welfare Act details proper treatment, it has no enforcement leverage. Moreover, only relatively small fines for violations of minimum care standards my be levied.

Finally, H.R. 6928 would extend assurances of humane treatment to all warm-blooded animals, protecting for the first time birds and the tens of millions of mice and rats used in research each year -- animals not covered under the current Animal Welfare Act regulations.

Although I have focused my comments today primarily on the provisions of H.R. 6928 that were adopted from my own legislation, I would also like to voice my support for Title I, which would set us on the right course towards finding the alternatives to animal testing that would render the rest of this bill unnecessary. I hope that day comes soon.

I have commented on only a few provisions of the bill. I hope you can see not only how necessary these provisions are, but also how reasonable. Mahatma Ghandi once commented that one could judge how civilized a nation was by the way it treated its animals. Passage of this legislation would help us move another step up that ladder -- ultimately benefitting not only the animals, but ourselves as well.

Mr. LELAND [presiding]. Mr. Lantos.

STATEMENT OF HON. TOM LANTOS

Mr. LANTOS. May I just say, Mr. Chairman, this is an unusual role for me to play, second to my wife, who certainly has taken the lead in this field.

I just would like to say a couple of sentences to my colleagues because I feel very deeply about this piece of legislation, which I view as nothing more than a step in a long overdue and neglected direction.

We are ostensibly talking about animal welfare, but in fact we are talking about the humane and sensitive quality of our society. I think it is important to recognize that we are really dealing here with a pendulum issue. In the field of animal welfare, the field of medical research, there are theoretically polar position.

One polar position would maintain that the importance of medical research overrides all considerations of animal welfare and no one is maintaining that position. The other position would maintain that protection of animals must be given priority, whatever the cost of medical research. And no one is maintaining this position. We are dealing with a pendulum issue. There is no question in my mind that the pendulum for long has been tilted against animals.

My good friend Congressman Dannemeyer raised the question of why introduce a new entity. May I say, if I could use an analogy in the field of the Foreign Affairs Committee, that the Foreign Affairs Committee for a long time had no subcommittee dealing with human rights. All of its subcommittees were geographic subcommittees and subcommittees dealing with economic issues and military issues. And, at long last, we learned that there is a human dimension to foreign affairs.

I think there is a feeling and sensitive dimension to this issue. And perhaps the legislation could probably be called the ombudsman for animals or perhaps the ombudswoman for animals because they certainly are entitled to one. The introduction of an ombudsman concept in many, many facets of private and public organizations at literally no cost and with no major threat to the ongoing function of those institutions has injected an entirely new attitude to the functioning of those institutions, and that is what this legislation is basically all about.

It questions the motives of no one. It questions the modus operandi of no one. It merely puts into the process where decisions are made a different outlook, a different viewpoint, a new angle, a new approach. And this is why I think some people who oppose this legislation find it so disturbing.

There were people in the foreign affairs field who felt that there is a military dimension to it and a political dimension to it and an economic dimension to it, and that is it. And some of us have fought for a long time to inject the human aspect into the field of foreign affairs. What we are attempting to do is to inject a humane facet to the treatment of animals. This is a checks and balances proposition, and an extremely modest one.

If I may, Mr. Chairman, I would like to have Mrs. Lantos give her statement, which is not mine, but I fully support it.

Mr. LELAND. We certainly agree with that. We welcome you,

STATEMENT OF ANNETTE LANTOS

Mrs. LANTOS. I am Annette Lantos, and originally it seemed to me that my husband was going to be unable to be here, so I was going to come to speak on behalf of myself and my husband. Now, I suppose, our statement is made on behalf of both of us.

Both my husband and I are survivors of the Holocaust and we both lost most of our family in that tragic and cruel backwater of history. As a result of this, we have become deeply sensitized against cruelty and callousness toward all living beings who have the capacity to feel and to suffer.

But we are without power to fight back and to protect ourselves. We believe that all forms of oppression and cruelty are connected and are symptoms of some great underlying feeling in our humanity. We believe the problems and tragedies of this world will not be solved until inflicting pain and suffering on helpless creatures will be the means to accomplish our goals, and until we remain convinced that the ends justify the means, whatever they might be.

Just as wars which inflict a great deal of suffering on humanity are not left to generals alone, so the war which goes on in the laboratories against disease ought not to be left purely in the hands of the experts. Just as we do not allow our foot soldiers to be needlessly and thoughtlessly sacrificed on the battlefield, so we should not allow the careless and excessive sacrifice of animals in our laboratories.

The issue is not scientific freedom but scientific accountability. Scientists, of course, must be concerned about science, as generals are concerned about winning wars. But both groups must ultimately submit their judgment to those who are not only concerned with the expedience of the situation but also with the profound moral dimension that is connected with these matters.

Both my husband and I were members of the academic community before we came to Washington and, therefore, we particularly resent the dichotomy which we frequently encounter according to which those who care for scientific research and those who care for animals are in separate camps. We do not think that this is the case.

On the contrary, we believe very strongly that there is an important need for public participation in the field of decisions pertaining to the care and use of laboratory animals in science. We also believe that ultimately this will benefit both science as well as humanity.

Just as an example, recent studies have shown that stress induced by inadequate handling and care affects metabolic measurements and, consequently, may seriously skew research findings. It is always, under the best of circumstances, difficult to extrapolate findings from animals to humans. It is much more suspect when stress induced variables are involved in the results.

The intention of H.R. 6928 is to insure a modicum of public participation in the care of laboratory animals. We believe this will ultimately lead to the advantage of both science and humanity. The priority for scientists, of course, must be science. The priority for those with compassion is the care of the animals.

But the priority for an economist like my husband is be
social, and the return we get for public money we spend on
tory research.

The issue that we wanted to raise here is the question of research design namely, what is intended by research and the research method; namely, how is it done. For example, we do not need to spend a quarter million dollars to blind cats in order to learn how their physical disability affects sexual performance in humans. We do not need to use repeated electroshock on animals to see that pain produces aggression. We do not need to spend research money to find out what we already know.

Nor do we need to spend money for poorly designed research that will tell us what we do not need and do not want to know. Such experiments only create and sustain disillusionment with both science and government in general.

Occasionally both my husband and I have the feeling, in studying this issue, that we are engaged in what the French call a dialog of the deaf. The scientists talk about their goals, the economists talk about money, and those of us concerned about animals talk about pain, suffering and cruelty.

We believe that this dialog of the deaf ones needs to be opened up so we can understand each other and see each other's point of view, so that we can see that we are not dealing here with an antiscientific crusade but merely with a rational approach of clearly defining what we need to do, the proper role of animals in research, and an expression of compassion for beings who sense and who feel.

From civil rights to women's rights, the history of the last two decades has been highlighted with dramatic and meaningful advances in the direction of a better and more equitable world. Rights and protection for animals is one of the last gaping voids in this. It is the final link without which our dream of a more decent and humane world cannot be completed.

In conclusion, I would like to take the liberty to share with you a few lines from my favorite poem for this season. It sums up everything I have been trying to say for the last 5 minutes.

The voice of the heart speaks the message so true,
Do unto others what you wish done unto you.
Kinship is all life, is the ultimate plan,
Protector and guider is the role meant for men.
So take care of the animals who speak without words,
Whose voices have value but are so seldom heard.
Give them your love, keep their worth in sight,
Merry Christmas to all, and to all a good night.

Mr. LELAND. Thank you very much, Mrs. Lantos.

I would like to address my first question to the gentlelady from Colorado, Mrs. Schroeder.

The research community argues that better research techniques are a byproduct rather than an intended outcome of research projects. Do you believe that NIH should target funds on such specific research techniques as tissue cultures or computer simulations?

Mrs. SCHROEDER. Well, I think being a lawyer I am out of my element in deciding exactly what they should do. I think the NIH is structured so that when they make those decisions they are looking at the state of the art. If the computer simulation is to the point where it is the same state of the art as the tissue culture, then I think they can make that decision. If it is not, if they do not have a

nerve synapse or whatever they need that they can reconstruct on the computer, then obviously you are wasting your time, if they insist that you are going to do it this way, because it will not work.

To be very honest, I do not know what the state of the art is in those types of things. But I think there are many things that we do not need to do that we are doing. I think Mrs. Lantos asks very serious questions about some of the kind of research that is going on way before you get to the computer simulation. And DOE has been some of the worst offenders of that, doing animal research in areas where they do the same thing over and over and over and over.

One of the questions becomes not so much either the computer or the tissue, but it becomes do you have to reconstruct the experiment every single year so the new group sees it, or can you write it up and say that if you do this to a blind rat it does thus and so. Or if you do thus and so I mean, you have to do the whole thing all over again.

I come from the law where we do not have to go and watch every single case. We read about some, the conclusions of some, and you store that in your data bank and move on from that point.

I think a lot of those decisions need to be made because the cost of research is phenomenal and we want to make sure it is always moving forward rather than just bogged down repeating the same old thing.

Mr. LELAND. How do we assure that higher standards for animal care will not inhibit good research?

Mrs. SCHROEDER. You know, the whole thing is you give women higher pay, you will bankrupt America; if you do affirmative action, there is no one qualified. There is some tyrannosaurus caucus out there that cranks out the same kind of scare stuff on anything that you want to do that may change the way it is. The defenders of the status quo always say that.

Again, the point is not the scientific community versus the compassionate community. The medical profession supposedly went in there because they have compassion and there is nothing in this bill that says that there will be no more animal research. Absolutely nothing. Nor are there limits on it. It is saying that if you do animal research you feed the animals, you care for the animals. You review the different research projects that are going on to see which ones are producing what they are supposed to and so forth and so on.

But it is not a mandate for the Federal Government that everything stops, and I think that is very important. So I just think that those kinds of scare tactics, that this is the end of it, as Congressman Walgren said, Fido versus you, I just think that that is all the same kind of stuff we hear in many different areas from the Flat Earth Caucus or whatever.

Mr. LELAND. Thank you.

Mr. WAXMAN. Any other questions? Mr. Walgren.

Mr. WALGREN. No questions.

Mr. WAXMAN. Thank you for your participation in this hearing today. Please forgive me for having to leave to go to the House floor. There is a rule being considered in caucus that I had some interest in.

Mrs. SCHROEDER. Thank you very much for having us.

Mr. WAXMAN. We will next focus on the provisions of H.R. 6928 dealing with the care of animals in research.

Dr. Bennett Derby is clinical professor of pathology at New York University. He is accompanied by Dr. Bernard Rollin, professor of philosophy at Colorado State University. Dr. Franklin Loew is the dean of the School of Veterinary Medicine at Tufts University in Boston.

Would you please come forward? We have your prepared statements and they will be made part of the record in full. I know my staff has talked to you about summarizing your testimony in around 5 minutes, and we would like to keep within that timeframe so we will have full opportunity for questions and answers.

Dr. Derby, why don't we start with you?

STATEMENTS OF BENNETT MARSH DERBY, A.B., M.D., PROFESSOR OF CLINICAL PATHOLOGY, NEW YORK UNIVERSITY SCHOOL OF MEDICINE, ACCOMPANIED BY BERNARD E. ROLLIN, PH. D., PROFESSOR OF PHILOSOPHY, COLORADO STATE UNIVERSITY; AND FRANKLIN M. LOEW, D.V.M., PH. D., DEAN, SCHOOL OF VETERINARY MEDICINE, TUFTS UNIVERSITY

Dr. DERBY. Since you have my prepared statement, all I will do is highlight portions of it. But then I would like to add to it with some quotes from some attachments which were also provided with the statement.

Mr. WAXMAN. Could you please pull that mike in a little bit? I think it is on, but it is just a little bit far away.

Dr. DERBY. I am not being heard. Yes, that is much better.

In brief, I have my own personal experience in several different ways having to do with animal research—the animal care, design, methodological execution, the administration that goes with it. And through the years I, of course, have had my share of hospital administration dealing with Government policies and so forth. So I look upon this whole area as a blend of experience in administration and animal work.

I have made a point that there should be no reason for undue anxiety on the part of impending impact of an unusual amount of money or staffing since an animal committee and accreditation and regular inspection have been in existence for some time. I also think it a wise provision to on the one hand study this for a little bit to see if there is an impact that is unanticipated and, on the other hand, let a few years go by if there should be some problem with renovation.

I think it is very important and should be very clearly emphasized that proper animal care depends in the first instance on proper animal quarters, second, proper operating facilities for the techniques that are to be used. It would be a strained academic research unit that with or without this legislation would not be in the steady process of revision and renovation of its physical features as a regular, built-in side of competent medical research.

H.R. 6928 goes further at important levels, going beyond husbandry. They wish to see that there is use of the least painful methods. We do not want to do anything but emphasize that there

is no intention whatsoever to intrude upon conceptual design, only the executory technical details.

Where pain need not be used or can be avoided, that should be done. The least number of animals should be used. The creation of ongoing prospective planning and reviewing in contrast to retrospective looking at previous reports is, I think, one of the most thoughtful creations embodied in H.R. 6928.

H.R. 6928 strikes at the twin paradoxes of good care expended on poorly executed or unnecessarily distressing techniques and, on the other hand, of useful research blunted by substandard care. This compass is carried out by H.R. 6928, as I see it.

The sensitive topics of reutilization of animals and work on animals which are totally paralyzed without anesthesia, perhaps necessary for the concept, are examples of things that need looking at—not the design of the physiological intent but the need to carry it out in that manner. I would never say do not do it. Although introduced properly as a pathologist, I am also a neurologist and there is only certain ways you can get at a study of central nervous system function. I am healthily aware of that. I am also healthily aware of the fact that with proper design, proper looking at it, this need not be done one bit more than is necessary for the aim.

It has been questioned earlier as to why, after all, with the existing framework for inspection should there be a necessity for tilling new ground in this area. I have attached to my statement samples of excerpts taken from USDA investigation, onsite inspection reports, and I will refer to the page numbers of the attachment, but such things as 40 monkeys in a breeding colony housed at night in two 8 by 10 pens; recommendation for a larger housing area. Repeat visit: too small for the size of the animal. Primates must have room for normal postural adjustments. And a previous recommendation had not been fixed.

Also, I should emphasize to you that it is sort of common sensical and physiological to allow animals to have a sufficient baseline area of movement. A repeat observation on a primate in cage that is 13 by 25 inches. You know, the primate is a nice word for a monkey, so that is 1 foot by 2 feet, forever—forever.

This is the sort of thing that is occurring that in fact does require effective regular inspection. Those who would say that there is an apparatus or a framework available are right, but it is not working. It should work. It needs revision. New legislation: the need for it is revealed as you go through these sheets, which I will not do further.

I would, however, since the element has come up of the need for new legislation, I have with me and can introduce, if permissible, a rather conveniently outlined H.R. 6928 and Animal Welfare Act comparison for the Committee's aid in making their own decision.

I will stop here.

[Testimony resumes on p. 68.]

[Dr. Derby's prepared statement follows:]

STATEMENT IN SUPPORT OF H.R. 6928

BEFORE THE SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

OF THE COMMITTEE ON ENERGY AND COMMERCE

BY BENNETT M. DERBY, M.D.

December 9, 1982

The proposed Act, H.R. 6928 on Humane Treatment and Development of Substitutes for Animals in Research, is a very important step in the right direction. As a medical school faculty member (a curriculum vitae is attached), I have personal experience with animal investigation in medical research. Features of animal research not widely recognized are how much remains unpublished, how free the investigator is from peer review, and how remote from animal care the scientist himself may be.

H.R. 6928 sets a meaningful standard for animal maintenance by accreditation. Criteria for animal care are already in force, and institutional boards for animal care are already in existence in institutions receiving NIH grants, making it difficult to understand why any anxiety about increased staff and funding exists, particularly when animal usage has decreased by at least 1/3 in a 10-year period. Naturally, those institutions not yet meeting the standards of the NIH Guide for the Care and Use of Laboratory Animals, adherence to which has been called for since 1963, may need time and budget to make progress, but this can scarcely be levied as a fault of this bill, H.R. 6928. A transition time of up to ten years permits utilization of customary ongoing renovative costs which would normally be required with or without H.R. 6928. The companion bill in the Senate, S. 2948, provides an interim study period of one year to verify the dimension of any impact by the legislation and gives the Secretary authority to waive certain accreditation

requirements in special instances. I recommend adoption of this amendment.

There is reason to suggest that any institution finding itself outside this framework financially has not been funding animal care properly in the first place. Moreover, under existing practice there is evidence that conformity with standards of animal care meeting Department of Agriculture inspection requirements is lacking in representative major institutions. Summaries of some of these will be provided. It is perfectly clear that H.R. 6928 is needed to guarantee the intent of Congress to assure humane care and treatment of animals used in scientific research funded by the U. S. Government.

H.R. 6928 goes further, however, at equally important levels, to promote use of the least painful experimental methods and the least number of animals and, with this, to foster alternative models and methods for equally serviceable results. My particular enthusiasm is for the thoughtful creation of a standard for prospective planning as well as operation in animal investigation facilities. H.R. 6928 strikes at the twin paradoxes of good care expended on poorly executed or unnecessarily distressing techniques, or of useful research blunted by substandard care.

This much needed compass is, it seems to me, effectively carried out by the institutional animal studies committee provided in the bill with scope for method as well as management. In the manner set forth, there is no intrusion upon the principles of animal research by a competent investigator, and surveillance of the practices serves the interests of the experiment and the animal alike. Such sensitive topics as re-utilization of animals and examination of the need for and manner of techniques used on paralyzed, unanesthetized animals, point up the importance of review of methods not only by colleagues but by an outside person representing community concerns for the welfare of the

animal subjects. Provision for such a committee, reviewing techniques without infringement upon design, and with a noninstitutional member, is noted with approbation. This mechanism already operates effectively in similar boards for human research and for community hospitals, with no compromise of mission. The properly mandated animal studies committee can bring needed diverse points of view on methods of animal research into alignment without disruption of basic activity.

The provisions governing the committee's work are well thought out, including a requirement for regular meetings with a quorum, semiannual inspections of all animal study areas, review of the practices in progress to ensure that animal pain and distress are minimized, and that deviations from originally approved methods and practices that adversely affect animal welfare are reported to the Federal granting agency.

Provision for minority reports to the agency and for individual members' reports to it, to the Department of Agriculture and to the accrediting agency, of persistent unacceptable conditions of animal care, treatment or use, and, finally, suspension or revocation of Federal support for the project, if the sponsoring agency determines this to be necessary, provide the necessary sanctions and incentives to treat the animals humanely.

A practical means of preventing mistreatment or neglect of animals is the requirement that the institution inform employees of the provisions of the legislation and instruct them to report violations to the animal studies committee without fear of retribution.

Important provisions of Title III include: (1) justification of anticipated animal distress in terms of the benefits of the research--a valuable means of provoking careful thought in the planning of the work; (2) veterinary medical advice in planning any experiment involving more than momentary pain or

discomfort; (3) proper use of anesthetics, tranquilizers, analgesics and paralytics--here I would recommend adding the words "control of" paralytics to make completely clear that drugs which immobilize without preventing pain must be most carefully restricted; and (4) avoidance of repeated painful procedures on the same animal, as has too often been done in practice surgery courses merely to save small sums of money.

Accreditation standards are properly tied to these provisions and wisely include exercise among the subjects on which appropriate and reasonable requirements must be made.

In conclusion, I urge this Subcommittee, which plays such a significant role in authorizing NIH funds, to seize the opportunity to ensure that those funds are used for research conducted in the most humane ways possible. H.R. 6928 has been studied and discussed line by line in a series of open meetings involving major scientific and animal welfare groups. It was overwhelmingly approved by the Committee on Science and Technology. It will reduce animal suffering and simultaneously reduce errors in scientific data. In fact, it is good for all concerned, with only one exception: commercial animal breeders and dealers who profit by selling as many animals as possible, spending large sums to promote their multi-million dollar sales, and who have, for selfish reasons, inspired undeserved negative comments on this moderate measure. Such self-serving activities are contrary to the public interest and should be given short shrift. The bill should be reported favorably so that the Congress as a whole may vote on it before this session ends.

SAMPLE EXCERPTS: U.S.D.A. INSPECTION REPORTS

SAN FRANCISCO BAY AREA ANIMAL RESEARCH LABORATORIES*

1979, 1980, 1981

STANFORD UNIVERSITY MEDICAL CENTER

OLD ANATOMY BUILDING

March 27, 1980

"The Old Anatomy Building is very old. It has been marginally acceptable in the past, but has now deteriorated to a point where it is far below minimal acceptable standards of the Animal Welfare Act. The walls: in almost every room paint is peeling from the walls. There are holes in the walls of room 8 - made by mice. There are large cracks in the walls of room 9. There are gaps between the walls and the floors throughout the building. The floors: the cement floors are cracked throughout the building. There are pits in the floor an inch deep in some areas. The ceilings: the ceilings of rooms 3 and 8 need to be painted. The door of room 4 has lost paint over half its surface. That door and its frame have been damaged by water. All interior surfaces of rooms used for animal research and housing must be intact and must be substantially impervious. This is necessary for proper sanitation and pest control... Rodents can enter the building and move between the walls and through the open spaces between the floors and walls. Numerous rodent droppings were found in the feed storage room, employees' shower, employees' locker room. Fresh droppings were seen in animal room 8. The animal care staff will not use the shower in that building because of mice in the walls behind the shower. The shower window is also broken...Proper rodent control in this building will be impossible until the condition of the walls and floors are corrected...There are missing light bulbs in several rooms... There are exposed electric wires in room 4. In room 15 (large monkey colony)...the waterproof cover over the light switch is cracked and there is water and rust around the switch. This is dangerous for anyone using the switch...The central heating and ventilation system is no longer functional. The only source of ventilation is through the windows, and this makes the rooms too cold. There are portable electric heaters in some rooms. But other rooms have no source of heat. These portable heaters could be a hazard to a loose animal in the room, and to personnel washing the rooms. Room 15 - indoor primate breeding colony is without heat and cold. Due to poor ventilation, the room had very high humidity even though it was cold. In hot weather, the humidity will probably be far worse...The drain pipe of the sink in the necropsy room empties onto the floor next to the floor drain. This sink should empty directly into the sewer line in a manner which would prevent contamination of the floor and walls by possibly infectious organisms. In interviewing staff, it was found that they have drainage problems also. The sewer lines are too small or partially plugged up...About 40 monkeys in the breeding colony are housed at night in two 8 X 10 pens. A larger housing area with more bars for rest and exercise is recommended to reduce fighting and stress among these monkeys. There are sheds behind the Old Anatomy Building housing squirrels. The drains in the sheds are reported to plug up daily. There are also numerous openings which allow entrance of wild rodents... The condition of the Old Anatomy Building is such that all structural

* Univ. of CA campuses (Berkeley, San Francisco & Davis) inspection reports are available in separate documents.

"deficiencies must be corrected or the use of the building phased out during the next 12 months."

ALL OTHER CAMPUS FACILITIES

March 27, 1980

"The first 3 deficiencies require immediate correction...Space requirements - primates: 2 primates in room 4 of the Old Anatomy Building and animal 396 in room 402 A of the Boswell Bldg. are in cages which are too small for the size of the animal. Primates must have room for normal postural adjustments and a floor space equal to 3 times the area of the animal when standing on 4 legs. These animals must have larger cages immediately...Primary enclosures: rabbits - room 407 A Boswell Bldg. - Cage doors were altered leaving a hole with sharp protruding pieces of metal. These cage doors must be made safe or replaced...Animal identification: about 6 dogs in quarantine had recently arrived from a pound and had not yet been given the metal USDA approved I.D. tags. Dogs picked up by the University must be given I.D. tags prior to leaving the pound. This applies to cats also...Drainage - the walkway from the dog kennel to Boswell Bldg. is used to exercise dogs while cleaning their runs. The cement surface is cracked very deeply. This needs resurfacing for proper cleaning of the area. As this is over an area used by the hospital, it is of importance in respect to human health. I feel this should be given a high priority...Interior surfaces: the floors throughout the Medical Microbiology Bldg. and in rooms 400 to 418 of the Boswell Bldg. are badly cracked. There are some holes an inch deep in the cement. There are gaps where the walls meet the floors in both buildings. There are areas in the Medical Microbiology Bldg. where the paint is peeling from the walls, and holes in the feed room wall and in room 121 of Medical Microbiology... The condition of the floors was pointed out in the inspection of 8/30/79... There is no improvement of the Medical Microbiology Bldg. yet.. The floors of the inside dog kennel area have a few cracks...Floors in squirrel cages are rusty (hard to clean - irritate feet of animals)...Throughout complex were several primate cages in need of regalvanizing - all rusty cages and cage floors need to be regalvanized or replaced. Rust can not be sanitized...Monkeys are locked outside during the day...There is no area covered to give shade or protection from rain in this pen...Cleaning/sanitation - Auditory Neurobiology: the floor is stained from water and possibly from urine and needs better cleaning. The cages can not be easily removed for cleaning - but are cleaned in place. To disinfect with steam or a pressure wash system requires removing monkeys from the building... Cleaning with hot water requires that the water be 180° and it is doubtful this is being done currently."

OLD ANATOMY BLDG., MEDICAL MICROBIOLOGY, PSYCHOLOGY PRIMATE BLGDS., JORDAN HALL, BIOLOGICAL SCIENCES, MEDICAL CENTER, SLAC, PHYSIOLOGY, ANATOMY

April 10, 1981

"The men's lavatory is not the proper place for the proper storage of bedding and food in order to protect it from contamination or infestation by vermin!...Observed covered can for animal carcasses outside door of Medical Microbiology. This was late Friday afternoon, the can was in the sun and not due for emptying until Monday. Three days in the sun is not conducive to minimizing odors or disease hazards...Cats - Old Anatomy Bldg. : no ventilation of room available. Jordan Hall, cats in room adjacent to room with bottle washer...may be excessive heat/humidity venting

"into cat room; ground squirrels. Old Anatomy Bldg.: ventilator fan extremely noisy when turned on - inoperable for ventilation; primates extremely humid, poor ventilation in room 9 when all primates are inside (poor even when all primates are locked outside). Inspection was on a cool day, conditions would be insufferable in hot weather. Ventilation must be made available - windows operable, operable fans, etc...If ventilation continues to be insufficient, will recommend removal of the animals from inadequate facilities...Interior surfaces of (A) Old anatomy Bldg. in deplorable shape...ceiling not impervious to moisture...ceiling not sanitizable...Room 15, cracked, peeling paint, dog runs...corkboard barrier with torn plastic sheeting...door margin damaged to bare wood, rusting metal plates, rubber seal fallen off...ceiling torn up by primates...broken and missing tiles, sheet rock tape peeling off...Animal room interior surfaces must be substantially impervious to moisture and readily sanitized...Observed cats in cages lined with newspaper only... Primates: in Old Anatomy Building, observed a primate in a cage 13 X 25 inches that does not provide adequate space for this animal. THESE PRIMATES MUST BE MOVED IMMEDIATELY AND IN NOT MORE THAN SEVEN (7) DAYS TO ADEQUATELY SIZED CAGES. Did not observe any changes in the available perching area in the inside cages of Room 9 as reported and requested by the previous report of inspection. Rabbits: observed many cages with 2 rabbits in them. Some of these rabbits are not provided with a minimal amount of floor space...These rabbits must be placed in cages with adequate floor space within thirty days...If overcrowding cannot be corrected, will recommend that the use of these animals be curtailed so long as this condition (overcrowding) exists... Observed caked feed in bottom of feed receptacles...Indicates inadequate cleaning practices...Observed algae in watering bottles...Investigator commented that it was good (nutritionally ?)...Algae in the watering bottles is an indication of inadequate and infrequent cleaning and sanitation practices...Institute a program of systematic, adequate cleaning and sanitation of water receptacles... Observed supposedly clean empty cages with feces/pellets in corners... Cages are apparently not moved out of the room for thorough cleaning and sanitation - cannot see where facilities in room are sufficient/available for adequate sanitization at least every two weeks. Racks are not being cleaned and are rusty even where cages are removable and cleaned in cage washer in some facilities. Rabbits are observed in cages obviously not cleaned enough to prevent urine...or excreta buildup. Rabbits are being splashed with wash water and/or acid during cleaning. Observed rabbits with sore hocks and soaked, matted hair masses. Primate cages have buildup of excreta, scum...Cages are not being cleaned up and sanitized at least every two weeks as specified in a proper manner with hot water of 180° F and detergent followed by a disinfectant. Observed squirrels in a cooler, when opened, had a strong ammonia odor - indicative that cages are not being cleaned often enough to minimize odor buildup or disease hazards, etc. Cleaning and sanitation in several facilities are far below minimun standards...If sanitation/cleaning cannot be maintained, recommend curtailment of use of these animals until minimun standards can be maintained...Observed mouse droppings in drawer in necropsy room, cobwebs in room 4...damaged doors in Medical Microbiology...rusty cage racks, hair and fur in ventilators...dirty light fixtures...paraphenalia in animal rooms (Bio. Sci.) including boxes, cans, watterbottles, window frame, insecticide spray, rack of unused cages in occupied dog run. Housekeeping needs great deal of improvement...Premises shall be kept clean and in good repair and remain free of accumulations of trash...Observed several "hazardous and potentially hazardous conditions - uncorrected since last inspection report. Necropsy room table drain remains open to sewer/drain fixture, ventilation fans open directly outside on walkways used by personnel and animals - esp. from the primate rooms and ground squirrels (hepatitis studies!)...Effective pest control must be initiated and maintained. VETERINARY CARE...THERE APPEARS TO BE A POORLY DEFINED LINE OF RESPONSIBILITY FOR THE VETERINARY CARE ON THIS CAMPUS. THE CONSULTING VETERINARIAN FEELS THAT THE LACK OF FEEDBACK OR RESPONSE BY THE RESEARCHERS AND MANAGEMENT TO THE VETERINARY STAFF SEVERELY COMPROMISES THE PROGRAMS OF DISEASE CONTROL, PREVENTION AND PROVISION OF ADEQUATE VETERINARY CARE. UNLESS THIS SITUATION IS CLARIFIED AND RESOLVED SO THAT AN EFFECTIVE LINE OF COMMUNICATION AND AUTHORITY IS ESTABLISHED TO FACILITATE THE CORRECTION OF DEFICIENCIES, PROPER VETERINARY CARE OF THE ANIMALS MAY BE DOUBTFUL [italics added]."

U.S. DEPT. OF AGRICULTURE INSPECTION REPORTS: U.C. BERKELEY; 1981, 1982

LIFE SCIENCES: MICROBIOLOGY/IMMUNOLOGY

July 1, 1980

"The authorized veterinarian does not feel at this time that he can provide the proper veterinary care as specified in the Standards, under current conditions. [This concession was recorded 17 times in the 1980 inspection reports dealing with almost every facility on campus.] Employees of this section...are ignorant of the details of the Standards and can only react to deficiencies when pointed out by inspection. Recommend that all employees responsible for animal care be properly advised on the Standards."

TOLMAN HALL: DEPT. OF PSYCHOLOGY

February 27, 1980

"Monkeys in room G 25 are fed by placing feed in waste pan under floor cage - no feeders present...In many rooms a buildup of feces and bedding on cages, on racks...on floors, in corners, on equipment (electrical, etc.) very evident...No regular observation of animals by caretaker under veterinarian's supervision. Some question of DVM even having access to animal quarters, let alone establish an adequate program of veterinary care."

March 5, 1980

"It becomes more evident that some cages and equipment are not properly designed to meet general requirements...Recommend a program to replace 'home made' and worn out caging...It is increasingly obvious that while the campus veterinarian seems to have the authority to provide veterinary care, the Dept. of Psychology is ignoring or challenging the matter."

June 3, 1980

"Dead beetles and rotting apples on shelves of refrigerator...Observed open waste containers used to transport garbage waste, dead animals, debris, etc. Waste observed scattered around docks...not handled as to minimize vermin infestation, odors and disease hazards...Room temperatures in many of the animal rooms cannot be maintained below 85°F because of lack of air conditioning and because of low air turnover...Adequate ventilation not present in many animal rooms...Primate cages are in a state of disrepair, including broken, protruding wires, inappropriately sized mesh (cats and primates), feeders cannot be maintained on the cages... Feeders on some cages are missing, resulting in food being placed on bottom pans where it is contaminated by urine and feces...Observed a general lack of sanitation...Cleaning, housekeeping and sanitation are in grave need of improvement...Observed large numbers of live and dead cockroaches in many rooms and hallways...Do not appear to be an adequate number of adequately trained employees to maintain an acceptable level of husbandry practices set forth in the Standards...The holding of different species in the same animal rooms constitutes a potential disease hazard in cross-infections."

ANIMAL BEHAVIOR STATION - DEPT. OF PSYCHOLOGY

February 27, 1980

"Some animals housed in outdoor pens in very poor state of repair and could result in escape of animals...Approximately 6 cricetid rodents left in pans on outside deck were drowned and left decomposing in pans... Outdoor structures and indoor structures in need of repair to protect animals from injury...Bldg. 5 contains fecal contaminated feed and bedding, dead mice...Equipment covered with feces and debris. Animals in cages on a filthy floor. Dirty cages and clutter in almost every room. Gross neglect in evidence...No program of health surveillance and veterinary care has been made with Campus Veterinarian."

June 11, 1980
"Trash barrels at side of road are uncovered and several are overturned with trash and debris scattered in ditch...Toilet facilities inadequate... The problem of veterinary care has not been resolved to date...No adequate provisions to handle dry waste are noticable...There is inadequate provison to protect animals from cold weather...There are evidences of rodents inhabiting the areas...There is no evidence of the capability to properly clean and sanitize the areas other than cold water hosing..."
June 25, 1980
"Outdoor facilities in which dogs are currently kept are marginal...Dogs are continually trying to dig out...Observed feed storage in metal shed on floor. These bags of dry dog food should be placed on raised pallets - off the floor to prevent contamination, dampness, etc. Potential for infestation by vermin exists...There is insufficient shelter provided the dogs in these outdoor pens. Observed one dog house...available for one group of bitches (9 head); two dog houses for the other group (18 head) - one of these was propped up on a slope at about 15-20° angle slant. There was basically no other shelter available except for some bushes. Adequate shelter for each and all the dogs must be provided...Major areas of this site are not usable for the dogs because of the overgrowth of foxtails and thistles - a severe hazard during certain times of the year. Dogs cannot be placed in several pens and even cannot be moved safely from one portion of the site to the other because of this problem. These dogs are therefore limited to the above described two pens. This constitutes an unacceptable hazard to these animals..."

BIOCHEMISTRY
June 25, 1980
"Observed exposed ductwork and fixtures with accumulation of dirt/hair/etc ..water bottles with algae...bottles on top of animal cages (with animals in them)...This reflects a housekeeping/cleaning problem with paraphernalia not properly stored or kept clean..."

WARREN HALL - SCHOOL OF PUBLIC HEALTH
March 5, 1980
"Premises are cluttered and dirty. Equipment and stores block use of sterilizer...Adequate sanitation of cages and equipment cannot be performed in this room and protect animals from being contaminated...No program of disease control and prevention and adequate veterinary care has been established or is in evidence."
June 11, 1980
"Area designated 'refuse room' is used to store bedding along with open trash barrels, cages and equipment, gas tanks, used transport cages, etc. The room is cluttered and filthy and infested with flies...Air turnover is reported to be inadequate - air is very humid...Almost impossible to maintain temperatures compatible with mixed species of chickens, mice, rats, guinea pigs, and rabbits in the same area with cage and rack washing...It should be noted that disease control is almost impossible with the inadequate physical plant - no species separation - no cage washing - no quarantine space - poor ventilation control. Repeat: progress report to correct these conditions overdue."

OXFORD TRACT - PLANT PATHOLOGY
June 30, 1980
"Storage of feed should be under conditions which adequately protect the foodstuffs - NOT immediately under animal cages...No temperature control. ...All food receptacles must be kept clean and sanitized at least every two weeks, not just when the rabbits are changed (upwards of several months). All watering receptacles must be sanitized...Primary enclosures for rabbits

"MUST be sanitized at least every thirty days, not just when the rabbits are changed (up to several months)...There are periods of time - particularly during the summer, when there is a temporary lack of sufficient employees to maintain the prescribed level of husbandry practices set forth."

DEPT. OF ZOOLOGY
June 26, 1980
"Many cages/primary enclosures of mice and chipmunks are stacked (offset) directly on top of other cages...This is a deficiency in husbandry practices and is a potentially hazardous situation of not providing sufficient ventilation...Several primate rooms showed no evidence of drains in floor ...Observed in Building 3 extensive cobwebs and dust in areas of the building adjacent to the primary enclosures, rips and tears in a sheet of plastic used to keep insulation from falling onto a cage from the ceiling. Hot water has been inoperative for some time...All of which indicates that the buildings and facilities - especially at Grizzley Peak are not kept clean and in good repair to facilitate good or prescribed husbandry practices."
October 23, 1980
"Area still very trashy - not corrected...Drainage from covered pen for Patas monkeys flows to covered entrance area - heavy fecal buildup...heavy fly and odor buildup."

MINOR HALL - SCHOOL OF OPTOMETRY
July 8, 1980
"All animal rooms and hallways have problem with interior surfaces...No longer impermeable to moisture nor readily sanitized...Repair of interior surfaces is essential...Several rooms have large numbers of cats loose in room as primary enclosures. Each time door is opened, cats must be pushed back to enter - hazardous to cats...Observed accumulation of dust/dirt in ceiling..."

DIVISION OF ANIMAL RESOURCES
July 18, 1980
"Observed several squirrels loose in animal room and trapped in capture cages...The housing facilities must be constructed as to protect the animals from injury and to contain them. Also observed in the same room, metal shelving on the verge of collapse, with badly sloping shelves on which cages with squirrels were placed...In storage rooms, observed trays with accumulation of feces/mealworm remnants...Rm 115 - strong odors in rabbit room, observed accumulation of fur on fixtures...Bat room (127) very poor housekeeping with feces/mealworm debris all over floor, paraphernalia/equipment, junk all over room, extensive housecleaning necessary. ...Racks with accumulated feed debris/dirt does not look like it has been cleaned or sanitized for some time...strong odors, bedding does not look like it has been changed for some time...Random check of identification on cats - one cat had two tags - one with a USDA number (62095) and also a U.C. tag of 528 - 528 does not correspond to this cat..."

OXFORD TRACT - CONSERVATION AND RESOURCE STUDIES
June 30, 1980
"There is no provision to provide artificial cooling for the outdoor rabbits when the temperature should exceed 90°F. At least one rabbit was reported killed by excessive heat during hot weather...Observed current cages in need of repair...Cages, feed receptacles, etc. not sanitized... This does not meet the standards of sanitation of primary enclosures... The rabbits are also used for public relation/information (4H type or 'petting zoo' activities) rather than research type activities...Inspector was not aware that this site existed with covered [by Animal Welfare Act]

"animals; does not appear on any lists of such sites."

DEPT. OF BACTERIOLOGY
March 5, 1980
"Observed ant infestation in several locations in building and several openings in the wall/floor junction that would permit entrance of vermin."
July 3, 1980
"Waste disposal: observed uncovered trash cans - inside accumulation of waste = decomposing material, very strong odor - not adequately cleaned... Observed caking of feed pellets in food receptacles...Construction of primary enclosures prevent sanitizing...Accumulation of fur, dust, feces, feed, etc., that indicate lack of through cleaning for some time...No response since previous report; not evidence of any action to correct deficiencies noted...Pest problem still same, still severe. Request immediate action...Sanitary facilities for employees not immediately available at site."

LIFE SCIENCES BLDG. - DEPTS. OF BACTERIOLOGY, MICROBIOLOGY, ETC.
March 5, 1980
"Numerous instances were observed in which cages had large accumulations of feces and strong odors of ammonia...Rooms cluttered with dirty instruments, equipment, corrugated boxes, cages with animals piled on top of other cages with animals, a rat running loose on the floor of one room...Animal surgery being performed in an overcrowded, cluttered dirty room with dirty animal cages, etc., etc."

WELLMAN HALL - DEPT. OF ENTOMOLOGY AND PARASITOLOGY
June 27, 1980
"These supplies are not adequately protected from contamination or infestation. At time of inspection, observed loose mouse in room...Admixing storage and animal facilities are not acceptable...Insufficient air ventilation ...Oversized rabbit in cage...Water at least 180°F not available, nor are disinfectants used for sanitation...This is unacceptable...Impossible to prevent cross-infection or have adequate disinfection when necessary... Hamster cages were on shelves used primarily for chemicals and equipment - storage and animal facilities are incompatible!...Above problems may be due to insufficiently trained employees and to reliance on work-study students = unreliable source of help."

ENVIRONMENTAL PHYSIOLOGY LABORATORY
July 1, 1980
"In primate room observed various breaks in interior surfaces including breaks in floor seal, cracks, peeling/flaking paint, cracks in wall, ceiling ...Interior surfaces at these points are no longer impervious to moisture and not readily sanitizable...Major fly control problem. May be related to lack of mechanical cage washer or sanitation/cleaning deficiency."

LIFE SCIENCES BUILDING - DEPTS. OF PHYSIOLOGY AND ANATOMY
July 3, 1980
"One of primate cages had both portions of perch broken - no place for monkey except on floor of cage or on bars. These perches must be repaired... Could see no provision for litter for cats-in runs with concrete/solid floors..."
August 4, 1980
"Previously recommended correction of providing litter pans for cats in kennels with hard/solid floors have not been implemented. Litter is not being provided at time of inspection."

1981 INSPECTION REPORTS

TOLMAN HALL - DEPT. OF PSYCHOLOGY
March 11, 1981
"Major deficiencies - many of the animal rooms showed major housekeeping problems...There was dirt, dust, cobwebs, trash, evident in many if not most of the animal rooms examined. This not acceptable...Appears to be a fly problem throughout facility...Observed roaches on walls...There appears to be an insufficient number of employees (and equipment) available to maintain the prescribed level of husbandry practices set forth...Cats are not being identified by collar with USDA or UCB number tags or tattoo. Twenty-seven cats not identified after being born on premises...Identification tags are being removed by investigators and not replaced, etc., etc. This is not acceptable."
May 28, 1981
"Drainage: rooms G7-11, 13 and hallway have a completely blocked, non-functional drain - impossible to adequately clean rooms or sanitize; strong odor problem, cats and other animals are adversely affected...Observed in G-35 (wild mice), sawdust and feed pellets all over floor - did not appear to have been cleaned or swept in some time...Improper storage of feed... rimate feeders not corrected yet...Recommend removal of animals from om and fumigation...Complete cleaning and sanitation of all cages, cluding primate cages, has not been accomplished."
ne 10, 1981
Ventilation - understand there are plans to increase the air flow an average of 25% - I question whether this increase will be available to the rooms and areas most needing the increased ventilation - On this inspection the poor ventilation and strong odors in G-55B were overpowering...The previously unblocked drains involving 3 animal rooms and the hallway were gain blocked; when water was put into the sink in the cat room, the sewer rain was seen to fill up to the floor. Adequate drainage is of major concern in the maintenance of animal rooms. Recommend appropriate action to correct this deficiency so that it does not remain a constantly recurring problem...Observed several live roaches previously noted in last report, also heavy fly infestation in several other rooms...Observed leaking water hose with puddle of water extending over floor and threatening to extend into hallway."
June 23, 1981
"o correction of deficiency of feed storage noted on last report; open g of feed pellets still on table top, festooned with cobwebs...Condition area an accumulation of trash, shredded paper, bedding-straw worse than fore...Still severe fly problem in some rooms...Observed hundreds of flies on feed containers, on walls, cages, etc....Report of alleged violation of the Animal Welfare Act will be prepared and forwarded for action."

FIELD STATION FOR BEHAVIORAL RESEARCH - DEPT. OF PSYCHOLOGY
March 12, 1981
"Beagle colony:...Outdoor facilities at this site are still marginal at best...Several primates have escaped recently...Sheet metal edges are turned out posing a significant hazard to the primates...Disposal of wastes, trash appears to be a problem...Nearly every room and building had an accumulation of equipment, paraphernalia, scraps, trash inside, outside, behind and under the buildings. Do not see any evidence of trash bins or organized method of trash removal...Primates in the pits were observed huddled around the one heat lamp available during the cold, wet weather - insufficient protection from the cold considering the condition of the facilities and the number of primates...Drains in the primate pits were completely blocked when observed, permitting considerable backup - no drainoff - and contamination of the floor of the sites. Combined with

"the fecal contamination mixing with feed pellets on the walls and floor - make for a thoroughly unsanitary and unsatisfactory condition for these animals...Facilities in general condition of disrepair...Basically not a suitable facility for the primates unless extensive repairs are made... Adequate sanitation of primate pits very difficult."
April 1, 1981
"Primate pits - NO CORRECTIONS OF DEFICIENCIES since last inspection - Request repairs to sheet metal hazards have not been attempted or accomplished...Report of alleged violation of the Animal Welfare Act will be prepared and forwarded for action."

DEPT. OF BACTERIOLOGY/IMMUNOLOGY
March 16, 1981
"'The interior building surfaces of indoor housing facilities shall be constructed and maintained so that they are substantially impervious to moisture and may be readily sanitized.' This site does not meet that requirement...The hot water heater observed on the site does not seem capable of 180° F hot water and did not see any disinfectant solution on premises."
May 7, 1981
"No change in interior surfaces since last inspection. No response as to intentions to correct this deficiency in the requested time...No intention to correct is implied...Observed dead guinea pig in one of the cages covered with ants and with an ant trail leading to the walls. This is unacceptable...Report of alleged violation of the Animal Welfare Act will be completed and forwarded for action."

WELLMAN HALL - DEPT. OF ENTYMOLOGY AND PARASITOLOGY
March 13, 1981
"Observed in mouse breeding room open bag of feed on the floor...Observed algae buildup in watering bottles for ground squirrels...Correct washing procedures to include disinfectants...For lack of space, animals and equipment are still being kept in the same areas...Undesirable situation."

ENVIRONMENTAL PHYSIOLOGY LAB
March 25, 1981
"Primates: Primary enclosures are not being completely sanitized in a prescribed manner every two weeks...The entire cage is not being sanitized as there are insufficient number of cages available to move the animals to. Cleaning and sanitation every three to six months is not acceptable... Observed severe fly problem in primate room."

LIFE SCIENCES BUILDING - DEPT. OF PHYSIOLOGY/ANATOMY
March 30, 1981
"Rabbits: Observed bottle of ear mite solution on cages next to rabbits in cages: Hazardous. Remove from proximity of rabbits and keep in proper storage immediately...Primate perches holding primates are broken again... Observed number of collars with USDA tags hanging on pipes in cat room - Numbers were assigned to dogs 3/79 and 4/79. Recommend that these tags be returned to Division of Animal Resources on disposal of dogs so that accurate records may be maintained; also, no record of disposal of these dogs available at Division of Animal Resources."

DEPT. OF ZOOLOGY - LIFE SCIENCES BUILDING AND FIELD STATION
March 17, 1981
"Premises have been cleaned but basic deficiencies noted in previous report unchanged...Observed accumulation of water in outside sink and mosquito

"larvae proliferating. Premises and grounds must be kept clean and in good repair."

MUSEUM OF VERTEBRATE ZOOLOGY
March 17, 1981
"Observed water bottles with algae accumulation and cages with more feces than sawdust in them...Excreta is to be removed from primary enclosures as often as necessary to prevent contamination of animals, minimize disease and odors."

MINOR HALL - SCHOOL OF OPTOMETRY
March 24, 1981
"Nearly all rooms, hallways have interior surfaces (walls) that are badly damaged...No repairs since last inspection...This is unacceptable...If corrective action is not undertaken, recommend removal of animals from such premises...Observed in Rm. 160-A twenty-one cats loose in room used as a primary enclosure (breeding colony), with only a perching box mounted on wall with sufficient room for 6 to 8 cats...Standards require that no more than 12 adult non-conditioned cats shall be housed in the same primary enclosure."
June 19, 1981
"Housekeeping is in disarray because of the need to vacate several rooms for the repair work...There are about 32 cats in this room including several in cages and there is not enough elevated solid resting surface available...A report of alleged violation of the Animal Welfare Act will be prepared and forwarded for action."

DIVISION OF ANIMAL RESOURCES
March 30, 1981
"Observed primate cage with layer of encrusted dirt - indications that cages are not cleaned/sanitized adequately or as often as necessary... Observed rabbits in room with defective thermostat...Observed badly leaking waterer, large accumulation of feces, bedding, urine on floor - does not appear to have been cleaned in some time."
May 29, 1981
"Observed dirty, encrusted primate cage...Apparently cleaning schedule was disrupted by holiday...Observed in room 229B and others, accumulation of dirt on walls, especially near vents, ducts, indicating that thorough cleaning of these rooms have not been done in some time (year or more?)."

DEPT. OF BIOCHEMISTRY
March 24, 1981
Observed open bag of alfalfa hay in store room; this should be stored in available metal feed bin or other container to adequately protect feed from contamination or infestation...Observed rabbits...obviously oversize for that size cage...Remove to available larger cages immediately."

WARREN HALL - SCHOOL OF PUBLIC HEALTH
March 11, 1981
"Different animal species are still housed in close proximity...Observed one portion of wall with surfacing damaged - starting to peel and separate from wall."

DEPT. OF ANTHROPOLOGY - FIELD STATION
March 12, 1981
"Observed in primate building non-operative radiant heater...The primates had no access to sufficient heat (heated enclosure or source of radiant heat)

"to protect the animals from cold...Previously noted hole in wall in basement of Building 7 where food is stored and occasionally sick animals isolated has not been repaired. Was unable to get in locked door but hole was clearly visable through window..."

April 1, 1981

"Could not see where these primates had available to them a supplemental source of heat in the event of cold, wet weather...Observed no feeding/food container; feed pellets are thrown on ground adjacent to and subject to contamination by feces and urine. Food shall be provided to minimize contamination by excreta. Request that provision be made to offer these primates their food other than on the dirt floor, i.e., provide a feeder off the floor."

June 11, 1981

"Primates - provision of additional source of heat for these langour monkeys as requested in last report have not been provided...There are several damaged, hazardous areas in the primate enclosures...Portion of middle pens had feed pellets on ground in such a manner that it appeared that they could become contaminated by feces...Previously noted hole in wall of basement of Building 7, which is used occasionally for quarantine of sick animals has not been repaired...In the future, unless this repair is made, any use of this area for animals will be deemed a violation."

July 2, 1981

"Shelter from cold weather...no change since last inspection...Correction of hazardous fencing and sheetmetal noted on previous report apparently has been corrected. HOWEVER, on this inspection, additional hazardous conditions were observed...Observed two monkeys on either side of the separating fence pulling up and damaging the sheetmetal panels in an effort to see each other."

Mr. WAXMAN. Dr. Rollin, we have your statement and will have it as part of the record. I understand you have agreed to wait until the question and answer part of the session, and we appreciate that very much.

Dr. Loew, you have a statement and that will be made part of the record. We would ask you to summarize it.

STATEMENT OF FRANKLIN M. LOEW, D.V.M., Ph. D.

Dr. LOEW. Mr. Chairman, members of the subcommittee, I am Franklin M. Loew, dean of the School of Veterinary Medicine at Tufts University, Boston. While I am also the current Chairman of the Institute of Laboratory Animal Resources of the National Academy of Sciences, National Research Council, also a member of the board of directors of the Association of Biomedical Research and a member of several professional and scientific organizations, I am here today not as a representative of any of those or of my employer. I speak simply as one member of America's large biomedical research and educational community.

It is my understanding, further, that today you wish to specifically discuss the provisions of H.R. 6928 rather than the more general issues surrounding the use of animals in research, teaching and testing, which were addressed last year in hearings chaired by Mr. Walgren, and I will not take up more of your valuable time with those more general issues.

Let me make it clear that I believe that the Congress correctly perceives that beneficial changes in the current settings for biomedical research using animals is desirable in view of many Americans. But it is not clear to me, however, that any one bill will ever satisfy all scientists as well as all critics. The question, therefore, is, Does H.R. 6928 come reasonably close to providing a productive environment for continued American excellence in scientific and medical research while at the same time being responsive to an emotional and important public concern? And does it do so in a cost effective way, given the current economic times?

In my view, title I, non-animal testing methods, is in the interest of both science and its critics, providing a set-aside mechanism is not implemented. As you know, animal use in both this country and England has been declining, according to Government figures in both countries.

Title II proposes that all research entities receiving a Federal award and most Federal research entities themselves become accredited as meeting the requirements of the NIH document, "The Guide for the Care and Use of Laboratory Animals," a copy of which I have here and with which you are familiar, within 10 years of passage of this bill.

I support the proposition that animals be cared for and used in accordance with this guide, but as a research administrator myself I wonder where the reported $500 million said to be needed to meet this provision will come from. I cannot emphasize too strongly my full support for sensitive, active animal care programs in all research entities, and it is my opinion that facilities are not as important in this respect as the professional, technical and scientific staff in assuring humane care and treatment.

Title II also proposes the establishment of an animal studies committee, not unlike the human subjects review committees now in existence for research utilizing humans, as I understand those committees. I hope members of the subcommittee recognize that as more and more universities develop research agreements with companies, agreements which often involve patent considerations and the continued search for patentable medicines and medical devices by the companies themselves, concerns are being raised about the release of confidential data to the proposed committee member responsible for representing community concerns regarding the welfare of the animal subjects.

Parenthetically I will add that committees are expensive ways of doing science and while there may be no better way, consistent with this bill's goals, I urge you to consider the use of delegatory powers by the committee in carrying out some of its proposed responsibilities.

As one who has been involved in the care and use of laboratory animals in both Canada and the United States for over 17 years, in both fine public universities as well as fine private universities, I know that not all animal use in research, testing and teaching involves flawless animal care or experimental technique.

Neither, however, is all or even most of it painful and agonizing. Scientists clearly must recognize their responsibilities to the animals they study, and scientists who fail to conform to prescribed standards of behavior should be subject to sanctions and, if warranted, regulatory or legal action. I do not equivocate about this.

Similarly, however, your attempts to improve the environment for the care and use of animals in research must be consonant with the proven, peer review system of assessing science on its merits, and not on its methods. Methods, whether animal or nonanimal, must lead to excellence in science and, it is hoped, to a better society.

The cost of carrying out modern research is high in dollar terms and sometimes in animal terms. I urge the subcommittee to study all the testimony it receives and to balance the interests of the animals, their advocates, and the progress of science in a scientific age.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you very much, Dr. Loew.

I think I will start off my questions with Dr. Rollin. Do you propose that all institutions have animal care committees similar to that at Colorado State? If an institution has a strong committee, do you believe it must be accredited as well?

Mr. ROLLIN. Well, I think that the accreditation and the committee address different issues. It is our concern at Colorado State University that some mechanism be established for self regulation of research which concerns itself with the care and proper use of animals on a day-to-day basis.

Accreditation, I believe—and my university believes as well—addresses itself much more to the long-term needs of science per se in the scientific community. So I really do not see these two issues as on a par.

Mr. WAXMAN. Dr. Derby, the major objection that I hear to this bill is that it requires all research institutions to be accredited, and critics argue that the obvious agency, the AAALAC, sets Cadillac standards. Do you agree that the standards are unreasonable?

Dr. DERBY. No, I do not. I think that there would have to be opportunity for those to be reviewed. There is a possibility the old military white glove on the top of the door thing might be reviewed if such a thing were present.

But by Cadillac I think we mean first class, and in medicine we do not permit it any other way. So although I understood what is meant, my response to that is positively not. What is right, not moralistically but medically is what does. Anything else does not do.

And, if I may be specious, your question implied that there was a choice of a Cadillac and a Chevrolet and a Jeep. I think the premise I would like to substitute is that in this line of work there is no such panorama of choice. We are not buying cars or betting on horses.

Mr. WAXMAN. Dr. Loew, how would you respond to the answer that Dr. Derby just gave me about the concern that these accreditation standards are what I termed Cadillac, meaning that they would be more than would be necessary for the standards to be reasonable to accomplish the intended purposes?

Dr. LOEW. As you know, Mr. Chairman, AAALAC uses as its set of standards the "Guide for the Care and Use of Laboratory Animals." This is published by the National Institutes of Health. Therefore, AAALAC is one way in which the National Institutes of Health receives assurance that indeed the requirements of the guide, which are requirements for any grant recipient in the first place, are being met.

The issue, in my view, is not whether AAALAC has higher or lower standards. The standards exist and are published and revised periodically by the National Institutes of Health. The issue, I think, seen from the point of view of some—not all, but some—scientists is whether making it mandatory is in some way a violation of the traditional way in which science sets the stage for its own progress.

I think what we are talking about here is an issue of whether the mandatory requirement for accreditation, albeit over a 10-year period, a 3-year period, a 50-year period, is consonant with the way science is developed in this country. And those who have expressed concerns about it, additionally, of course, are concerned about the money.

As you well know, money in the end is one of the fundamental questions about assessing priorities. The issue is, are the conditions under which animals are used—not only research, by the way, but for teaching—at most of the universities in this country and in testing by regulatory agencies, is the investment in funds which is said to be $500 million and I am concerned about the accuracy of that number as well, cost-effective? I think some work needs to be done on that estimate of $500 million to see how accurate it is.

I am concerned that that is what is bothering scientists and research administrators somewhat more than whether AAALAC has "Cadillac" standards. The standards are those of the NIH at the moment.

Mr. WAXMAN. First of all, Tufts is AAALAC accredited.

You seem to have some question about the NIH figure of $500 million to meet the standards for all institutions.

Dr. LOEW. I do not question it in the sense that I have special knowledge that would refute it, but rather where that number comes from. At least the only place I have seen it legislatively is in the report of Mr. Fuqua's committee when it was looking at this bill previously, and there is a letter from the Congressional Budget Office document in that report which I am sure Mr. Walgren is aware of which uses that figure.

I have not studied the basis for the generation of that figure, and I would think that those of you responsible for considering this legislation would want to look at the basis for that.

Mr. WAXMAN. Dr. Derby, do you have any comment about that $500 million figure?

Dr. DERBY. I pretty much approached it already, but I would like to first thank my colleague for bringing out the need for inspection.

Second, I really believe that differing views would immediately vanish when there was mutual inspection of the basis for the figures. I could go further. You know that if you want to pump up things you take faculty time, which is ordinarily done free, as part of their duties, and you say that oh, this man now, out of nowhere, is having to put in x hours per week or per month, when maybe he was anyhow.

Now you are going to bill him out at $200 an hour. This artifice is a leading example of how you can blow numbers anywhere you want. In terms of hard capital there already are supposed to be decent animal facilities with decent inspection, a review program. I have already previously discussed the ordinary, ongoing physical plant aspects.

The rest, in my view, becomes necessary professional academic work that occurs in any medical school or medical school associat-

ed hospital. The only opening left for our blowup to hundreds of millions of dollars, it seems to me, might come about from some equally debatable high-set cost of having the accreditation visits carried out.

I believe that figure could and would be low certainly negotiable nowhere near hundreds of millions of dollars. We all agree, let's see what the data are.

Mr. WAXMAN. Mr. Dannemeyer.

Mr. DANNEMEYER. Thank you, Mr. Chairman.

Let me commend you for holding these hearings relating to the protection of animals which are used in research.

I am not being facetious when, preliminary to my questions, I make an observation as to the status of the culture as reflected by the American people insofar as they are represented by Members of the House of Representatives, because the record will show that during the course of the 97th Congress, numerous Members have introduced amendments to the Constitution on the subject of concern for human life that is being aborted to the tune of millions a year in this Nation today.

The record will show that those proposed constitutional amendments are buried in a subcommittee of the Judiciary Committee of the House, and I find that an interesting paradox. We, as an institution, manifest this needed concern for the care of animals while at the same time we, as an institution, cannot exhibit at least enough courtesy for the lives of the unborn humans in the form of hearings on the proposed constitutional amendment. I just find that an interesting paradox.

I do not expect an answer to that, but I think that statement needs saying in this hearing this morning for the sake of perspective, if for no other reason.

Dr. Derby, I noticed you said that these primates are being housed in conditions that are inimical to their good life.

Dr. DERBY. So the report said.

Mr. DANNEMEYER. I would like to have your observation as to if there is a particular reason why the administering of this new program cannot take place under the existing authority of the Animal Welfare Act as it is administered by the Department of Agriculture. Is there something about the legislative need which exists in our country that dictates that it only can be administered by a new division of authority, the HHS?

Dr. DERBY. I think I understand your question and like it, but I would like to make very sure I understand it.

What you may be saying is, if I were momentarily to be given the same scope and details of the current proposed legislation, you are saying could another arm of Government, such as the Department of Agriculture, carry it out, rather than HHS? Is this what you are saying?

Mr. DANNEMEYER. The reason being is that presumably the Department of Agriculture over the years has established an infrastructure for administering existing law concerning the welfare of animals in this country.

My question is, is there something about the legislative need which requires that we get another Federal agency separately involved in administering the same type of jurisdiction?

Dr. DERBY. Here is where my expertise needs to be joined to yours. I know little or nothing of Government and I am here today espousing certain principles which I have discussed. Subject at all times to my lack of sanity when it comes to knowledge about Government, I would agree that the principles, if carried out, I see no reason that logically the Department of Defense couldn't do it.

You brought up the Department of Agriculture already has an orientation and a staff for this. They have the orientation, but they do not, sir, have the staff.

Mr. DANNEMEYER. Well, is there something about the proposed addition of staff that this legislation contemplates that cannot be administered by the existing bureaucracy of the Department of Agriculture?

Dr. DERBY. I am doing a cross between fencing and ducking. I simply have no strong feelings about which department and for what reason this might be assigned. I am saying that wherever it goes these are the things it should have. That is all.

Mr. DANNEMEYER. Dr. Loew or Dr. Rollin, do you care to comment?

Dr. LOEW. If I may, I would like to comment briefly. Many people, including many in this room, believe that had the Animal Welfare Act been appropriately funded by those in a position to do so, we might not be here today.

The fact of the matter is that when that law passed in 1966—enacted in 1967, amended subsequently—when that series of events took place there was great optimism both in the scientific community and in the so called animal welfare community that there was a national structure in place sensitive to the needs of scientists and sensitive at least to some of the concerns of the critics about the way animals were used.

The fact is, Mr. Dannemeyer, that many people believe that the U.S. Department of Agriculture, for whatever reasons—budgetary constraints, pressures from places one cannot see, et cetera—has not been able to put the kinds of resources into enforcement.

My own personal view has been that at least Representative Schroeder's bill last year took the point of view that enhancement, enrichment of the funding and some of the authorities under the Animal Welfare Act was indeed a reasonable and logical way to go. If I may speak candidly, I believe there has been some disagreement as to whether USDA is committed, for whatever reasons, to enforcing that act.

I myself testified at budgetary hearings before House and Senate Committees on restoring the proposed funding cuts for the enforcement of the Animal Welfare Act. In fact, so far as I know, I was the only representative of the so called educational and scientific communities to do so. I believed in that act. I believe that it, like anything, can be improved, but its problem has not been, in my view, its language, although one can always improve it but, rather, the ability of the U.S. Department of Agriculture to appropriate and commit funds to it.

I do not say that in a critical way, Mr. Dannemeyer, because I do not sit in the hot seat of giving out USDA money, but your point is well taken and I am sure there are others in this room who feel this way.

If, however, it is the judgment of this committee and others that it is time to give up on the Animal Welfare Act for whatever reasons, you obviously will look at this vehicle. I think you have struck a very important note, however, in asking the question of why the present framework cannot be appropriately modified, improved, changed or whatever.

Mr. DANNEMEYER. Dr. Rollin, do you have any comment?

Mr. ROLLIN. Yes, sir. I would have to say it would involve a major conceptual change in the Animal Welfare Act. In the first place, of course, the Animal Welfare Act disavows any concern with the actual conduct of research. It has no mechanism for setting up a local review committee and so forth, whereas this act does deal with the day to day actual conduct of research and attempts to generate a new concept or, rather, a new concept in the animal area analogous to what we do with human beings.

Furthermore, you have to extend the scope of the Animal Welfare Act rather considerably, for at the moment, as you are probably aware, it excludes rats, mice, and birds from its purview, whereas this bill would include all warm-blooded animals.

Furthermore, I cannot really see any way in which the alternatives mentioned to this bill would be augmented by appeal to the Animal Welfare Act, nor to the very, very positive step which is indicated in this bill for the local review committee to establish courses in educating researchers as to the proper use of animals.

If I may just add one point to that, as I travel around the country talking to animal laboratory veterinarians I am informed that one of the chief difficulties resulting in pain and suffering for animals stems from the lack of researchers' familiarity with how to handle animals.

At one institution, for example, a researcher called in a lab animal veterinarian because the guinea pigs were dying of what he thought was a disease. It turned out, in fact, that it was simply malocclusion improper meeting of the teeth so the animal could not be nourished.

This bill mandates courses and educational activities within the institution to raise researcher understanding of how the animals function.

Mr. DANNEMEYER. At this point, is there in the veterinary world of our country a private organization that concerns itself with the establishment of standards for housing of animals or, for instance, at a veterinary school or in the research world? Is there an organization that ethically concerns itself privately with standards to be followed by people conducting research on animals?

Dr. LOEW. Yes, indeed. In fact, the official adviser to the U.S. Congress, a private organization chartered President Lincoln's government, the National Research Council of the National Academy of Sciences is indeed the private organization which generates the standards documents, the very Guide to the Care and Use of Laboratory Animals, which is referred to as the basis of the standards in the proposed legislation.

Mr. DANNEMEYER. Conceptually, couldn't we just say that since you are the professionals and you are going to develop these standards that you in the private sector, using the ethical judgment that you have acquired in your profession to develop the standards, and

then set up a certification process in the industry whereby you would ethically police yourselves or laboratories passing muster with the standards your profession has established?

And after you have gone through that process, you can just send your work product to the Department of Agriculture or the Department of HHS and maybe we can avoid the imposition of this bureaucrat's dream. Raymond Shipash, who has estimated that if the Federal Government gets involved in this program it would cost $50 million a year over 10 years, or $500 million.

Mr. WAXMAN. We can have an answer to that question. I would like to move on to the other members.

Dr. LOEW. The voluntary system is in place and, as we have heard before, several hundred research entities are already accredited by an accrediting body using these standards.

Mr. DANNEMEYER. Privately organized?

Dr. LOEW. Yes, indeed.

Mr. DANNEMEYER. Mr. Chairman, would the other members of the panel care to make a response to that last question?

Mr. ROLLIN. I should like to speak to the AAALAC accreditation because, as has been mentioned on a number of occasions this morning, no one is really sure how much it would cost.

But if I may respond to the cost of the institutional review board, we worked up these figures at Colorado State University, and we concluded that project review we are making the assumption that every federally funded institution has an animal care committee as a standard. To extend their work to project review would cost the Colorado State University, where we have almost $6 million in biomedical research, would cost approximately $1,500 a year for an additional 12th time secretarial help.

This would increase the cost of the committee, which is now forty-three one-hundredths of 1 percent of the biomedical research budget, to forty-five one-hundredths of 1 percent of our biomedical research budget.

Mr. WAXMAN. Excuse me, Mr. Dannemeyer. Under the rules, we have to go to the other members, but we will give you another opportunity.

Mr. DANNEMEYER. I would be happy to observe that. I thank you for your indulgence in time. You have been very kind.

Mr. WAXMAN. Mr. Walgren.

Mr. WALGREN. Thank you, Mr. Chairman.

I would just like to continue along the line of what our experience has been, and perhaps Dr. Rollin is the one to initially address that kind of question to.

Colorado State University has had a relatively active program in animal care committees and the like. The bottom line in this whole exercise is what are the extra costs, what are the benefits, and what are the detriments.

So my question would be: What has been Colorado State's experience in this area? What position do they take toward the legislation? What has been the experience as to extra cost, and would this way of going forward inhibit research in a way that would be detrimental to the scientific pursuit?

Mr. ROLLIN. Let me first begin by stressing the fact that Colorado State University is a major center of biomedical research. Our

researchers are the cutting edge of contemporary bio science. Just as an example, we are currently involved in animal studies dealing with such problems as cancer, leprosy, tuberculosis, low level radiation, malaria, hypertension, hip joint replacement, embryo transfer, and recently we achieved international recognition for cloning successfully the first pair of twin calves.

It is our view that precisely because of our deep involvement in biomedical research there is an onus upon us to develop a practical and rational approach to synthesizing the requirements of science with our deep moral obligation to the research animals we use. So actually it must have been about 6 years ago when a group consisting primarily of Colorado State University people got together and tried to set up ideal legislation which would balance a series of principles.

What they were trying to balance was, on the one hand, of course, the immeasurable human benefits which are derived and animal benefits which are derived from animal research and, on the other hand, our moral obligation to animals. We felt that the best way to do this was to develop local concern, local accountability with these questions on the analogy of what is done with the human research committees upon which I serve and, in fact, which I chair.

We felt that the burden of responsibility should be on the people doing the research and also that this would serve as an educational function which would raise the consciousness of research concerning these issues. In fact, we felt that there was also a positive benefit as far as research was concerned.

We find a lot of lurid what I might call "science fiction" concerning the sorts of things which allegedly go on in research institutions. If you open the doors to research institutions, bring in an outside member, show the public that what is being done in this place is not questionable, is something which could be explained, everybody benefits. We have not yet embarked upon actually reviewing projects, but we have adopted essentially the system which is described in the bill.

I think it is interesting to mention what the researchers said when we discussed implementing this sort of thing. One scientist said, and I quote, "We have nothing to hide. No one could be opposed to this unless they had something to hide." Another said that "rather than impeding us, it will help immeasurably in informing the public as to what we are doing."

I have, in addition to my appointment in philosophy, an appointment in physiology and biophysics, and my chairman, Dr. Robertshaw, who is an internationally known physiologist, and who serves on the public affairs advisory committee of the American Physiological Society, said, "The research community must have an institutionalized conscience which is not dependent upon the happenstantial interest of an individual like myself."

It was also felt, as was remarked earlier on a number of occasions, that review of the day to day process concerned with the actual use of the animals would help minimize the sources of stress which can well invalidate research. Good treatment of animals, I think, and the University would endorse this, is not a gift which science bestows on animals or can withhold when it feels like it.

It happens to be an absolute precondition for the validity of scientific results, as well as a more moral requirement. So it is a happy circumstance that our moral obligations and our practical requirements go together hand in hand.

In terms of costs, I believe I just addressed that to Mr. Dannemeyer's question. I have contacted and been feverishly on the telephone since I was called to testify trying to ascertain what other institutions or other scientific organizations feel about it.

I have talked, for example, to USC, where they have had a review committee of this sort extant for some time. They said their cost increases were negligible. I talked to the University of Florida. They said their cost increases were negligible. I found no one who would cite any significant increase in their costs by virtue of project review of the sort outlined in the bill.

I think it is very relevant to mention some of the responses I got on the telephone from the scientific community, with your permission. This from the American Physiological Society, Dr. R. Reynolds, and it is especially significant because the Physiological Society has often been seen as opposing anything having to do with the regulation of animal research. Let me quote this:

> The American Physiological Society supports the concept of local review as described in the bill and endorses the notion of intellectually credible outside members from the community.

Dr. Gillette of the College of Veterinary Medicine at the University of Florida endorsed the above statement when I read it to him yesterday. The following from the California Veterinary Association is relevant, as to the relevance of an outside member:

> There are many honorable foxes, but they are still foxes. So the California Veterinary Medical Association supports meaningful local review with outside members from the community.

That is from Dr. Noel of the California Veterinary Association.

Lastly, I think it is worth mentioning what USC said on the basis of the fact that they probably have the longest experience with this in the country.

> The University of Southern California regards an animal ethics review board with a member from the community as an indispensable mechanism for assuring balanced judgment of biomedical research needs and assuring highest ethical standards in the humane care and treatment of laboratory animals used in the research process.

I think it is interesting that for the first time that I am aware of in our history we have both the scientific community and those concerned with the welfare of animals agreeing on a fundamental mechanism for providing moral direction in the research process.

Mr. WALGREN. Thank you very much, Mr. Chairman.

Mr. WAXMAN. Mr. Leland.

Mr. LELAND. Dr. Derby, this bill mandates the review and approval of characteristics associated with and related to specific research protocols, not to the central animal care facilities and personnel. Is this not the domain of qualified reviewers as new projects are proposed rather than by accreditation teams at periodic site visits?

Dr. DERBY. Good Lord, no.

Mr. LELAND. Well, the animal study committee provision has no provisions for the expertise of the individual members. Therefore,

will these committees be able to make the sophisticated evaluations on a wide range of experimental design or comment on the need to use animals?

Dr. DERBY. Thank you so much for asking that, because one of the key problems, as with anything, is definition. I think there is an attempt here, not with any other intent, but to blend the researcher with the care. Now medical research devolves upon care, of course, but when we are speaking about the people who do it, we speak about their funding. You cut across several different lines.

The investigator himself, if you think about it a minute, has not one reason to ever, not once, never go to the animal room or himself carry out the experimental technique whatever it is. Were you aware of this? And you have heard the word "delegation" used. We use it administratively and conveniently. It is used in research as well.

Some of this is essential. No investigator is going to live in the animal quarters 24 hours a day. There must be animal care technicians, but they, of course, are paid through funding channels that will be different from the investigator or his associates. Somewhere around, there is a veterinarian. There has in fact never been any coordination whatsoever, and currently the only thing that is available is an examination of the husbandry itself with none of these other considerations which you brought up being brought into line.

So the question you have asked, in answering it, I hope I have explained the diverse points of view that are built into the situation, all of which need to be brought into alinement. Hitherto, only one arrow has been inspected the cages and is there enough food. This legislation would permit us properly, still sparing concept, to examine all the other vectors that go into conducting proper research.

Mr. LELAND. One last question, Dr. Derby. The use of conscious animals, a consulting veterinarian would have to be employed in the planning procedures. Are there enough qualified veterinarians in this country to fulfill this stipulation?

Dr. DERBY. I have a very, very firm idea that there is an enormous number of veterinarians that could fill this kind of need, with the proviso that if you were to narrowly define the criterion as only a veterinarian personally that has had previous experience with this form of research activity, then there might be three in the country. And if we were to sharpen it even further, and restrict it, there might end up being only one.

I think that the proper qualification of a veterinarian is not whether he himself has been involved in that kind of research but whether he is trained in animal physiology, including perception of pain, and whether he is trained in how animals look when they are responding to pain. We are staying away from design; we are only speaking of methods.

Any properly qualified veterinarian can do that. I believe there are several hundred thousand of them in the United States.

Dr. LOEW. With great respect, speaking as the dean of a new veterinary school, Dr. Derby errs significantly in his statement and I can correct it later, if you wish.

Mr. LELAND. You may respond now if you want.

Dr. LOEW. The fact of the matter is, of course, that I support the use of veterinarians in research laboratories. I also, by the way, believe that this bill is not an unreasonable bill in most of its aspects. Whether it should be part of the Animal Welfare Act or a free-standing bill is another issue that came up previously.

There are, as a matter of fact, only about 45,000 veterinarians in the entire United States. That compares, for example, to about 600,000 lawyers for whatever that is worth.

Mr. LELAND. A point well taken.

Dr. LOEW. Perhaps that speaks to the priority of animals, as viewed by American society. The fact is also that there are specialties within veterinary medicine emerging, as they have emerged in human medicine. There are specialty boards, and there is a field known as laboratory animal medicine, which has its own additional examining and certifying requirements, and there are approximately 400 such veterinarians certified out of the total of about 45,000 in this country at the moment, Mr. Leland.

Mr. LELAND. Thank you, Dr. Loew.

Dr. DERBY. There are two sentences. I am off by one digit, but 45,000 is quite enough for the few hundreds of research institutes. I myself am involved in postgraduate training of that specialty of veterinary medicine known as animal neurology and I am quite familiar with how even fewer of those there are than laboratory specialty practitioners.

What we do, of course, is teach somebody when he goes through veterinary school to know his anatomy, his physiology. We have found that in neurology we always have them instilled in those general principles. Those that want to practice nothing but neurology in animals, if there are more than just a few of them, they all starve to death.

I think that laboratory medicine is here to stay and I support firmly what he says. But I wish to also have it understood that you do not have to be a neurologist to tell if an animal is in pain, period.

Mr. ROLLIN. May I respond for a moment?

Mr. LELAND. Why not?

Mr. ROLLIN. I just wanted to say that we should keep in perspective the fact that every institution now doing biomedical research which is funded by the Federal Government has in fact a veterinarian on the committee who officially is credentialed, sufficiently credentialed, to address him or herself to the issues that you raised.

Mr. WAXMAN. Thank you.

Dr. Rollin, you have talked about negligible cost for these review boards. Isn't the real concern the amount of cost that would go into the facilities? I have before me a letter that you may have seen from Dr. William F. Raub, Associate Director for Research and Training of the Department of Health and Human Services. He refers in this letter to that $500 million figure, which is based on an Institute of Laboratory Animal Resources survey conducted in 1978, under the National Research Council.

He cites 10 million net square feet of laboratory animal facilities are in use, and approximately 38 percent of this space was reported

to be in need of remodeling, another 16 percent to be in need of replacement. Isn't that the costly part of the legislation?

Mr. ROLLIN. Oh, I would agree with that. This is why my university, in addition to the more conceptual reason for separating the local review concept from the accreditation concept, there is also this fiscal dimension. So we would like to separate those two aspects, and I am here on their behalf speaking for the local review committees.

Dr. DERBY. With or without this bill, that identical process goes on. That has nothing to do with this legislation whatsoever. This is a red herring. In other words, the renovation, the alteration, the expansion, the tearing down that goes on in any proper facility. That is not going to be a cost brought about by this legislation.

Mr. WAXMAN. I thought it would be a cost that would be brought about in order to be accredited as an institution under this legislation.

Dr. DERBY. Or if some of these places to become accredited have fallen so far behind, that they were not doing it properly in the first place, I would not view that as a direct result of this legislation.

Lastly, I think the transition period of time to which I have referred in my original statement brings all points of view into line with or without the legislation over a projected 10-year period of time. There is no research facility that is not remodeling, redesigning and renovating. There is no such thing.

Or you will please read carefully some of the hydraulic and rustic details in those attachments, and you will see there are falling down buildings that are being used. And yes, the louder they scream, the farther behind they were, not from legislation, but from anybody's standards of competent animal research practice.

Mr. WAXMAN. Thank you.

Mr. DANNEMEYER. Could I just ask a short question to Dr. Rollin? If I heard right, you estimated it would cost $1,500 to your facility in Colorado to comply with this proposed legislation?

Mr. ROLLIN. With the review committee aspect of it.

Mr. DANNEMEYER. Is that per year? Is that a one time startup cost?

Mr. ROLLIN. Per year just for the extra secretary.

Mr. DANNEMEYER. It is interesting by way of contrast to notice beauty through the eye of the beholder. The document to which I referred earlier is a work product of the Congressional Budget Office, which is required under our law to give an estimate of the cost of the proposed legislation, and the writer of this particular report, Raymond Shepich, for Alice M. Rivlin, Director of the CBO, no less, observed that it would cost the institutions of America $500 million, or $50 million a year over 10 years.

And if I extrapolated correctly, it is about 660 of these facilities in the country, so in the eyes of the CBO, it would cost your facility $75,757 to perform a service that you say you can perform for $1,500.

Mr. ROLLIN. No. We are talking about apples and oranges here because I was addressing in my remarks only the review of projects by the animal care committee, not the renovation of facilities.

Mr. DANNEMEYER. Well, you know I am impressed by the fact that you have in existence a professional organization which concerns itself with the setting of standards. I commend the members of your profession for that.

It strikes me that we are in an era today in this country where addressing this concern, which our colleague from Pennsylvania has brought to our attention and which is a legitimate one and I respect that, it would serve the taxpayers of the country better perhaps if your professional organization would set standards of accreditation and organizations that meet that standard would then be certified by your independent organization and then perhaps we could have a Federal law which would say if you want to get Federal research money you must have the certification of this private professional organization, because those people ought to know what they are doing.

If we did that by legislation, we could avoid $250,000 a year for five staff people who would be permanently ensconced in NIH for the purpose of looking down your throats as to whether or not you are properly conducting your affairs.

Mr. WALGREN. Would the gentleman yield?

Mr. DANNEMEYER. I would be glad to.

Mr. WALGREN. I think this may be an example of how close everybody is. The guts of what you just described as the way we should go forward is exactly what this bill does.

Mr. DANNEMEYER. Except, if you will permit me, your bill, if I understand it, says that the accrediting agency must have the approval of the Secretary of HHS.

Mr. WALGREN. He would designate or delegate that authority to an organization or organizations and we would accept their standards. He would look at their standards

Mr. DANNEMEYER. Subject to certain conditions that would meet the test of that particular individual acting on behalf of the Federal Establishment and those conditions can get very interesting and extensive.

For example, just out of my mind, it is desirable in this world to expand medical research with animals. Therefore, in order to encourage that one of the conditions could be that any facility had to have an intern program whereby you encourage through scholarships the training of people in your facilities and, whether you like it or not, it is one of the conditions that you can contemplate.

I am just making one out of my head as I am sitting here, but it is an example of how Government works in administering affairs to improve the quality of our lives, and all this costs money.

Mr. WALGREN. If the gentleman would yield, it seems to me what you are raising is the prospect that the Government would require more than basic standards of humane care.

Mr. DANNEMEYER. There is little doubt in my mind that that would be the case.

Mr. WALGREN. In creating power in an agency of Government to require more than perhaps we should? I think we ought to look at that because our purpose in this bill is to set minimum floors and the intent of the bill is for the Secretary to broaden present standards of performance.

Forty-five percent of all Federal moneys go to research entities that meet the standards called for in the bill. It is not our intent to go farther or to create extremely arbitrary powers. Perhaps we can talk about a way that would satisfy that reservation of the future horror story regulation.

But what interests me about this bill is that I see us as moving away from a very difficult way of regulating, an invasive way of regulating, where we send a Federal employee to inspect and deny approval from the outside, to go into an agency and withdraw their certification or the like. I see us moving away from that to a way to call attention of these research entities to basic standards and a structure within the private sector which is inclined that way and which has the incentives to move in that direction.

Mr. DANNEMEYER. Thank you very much for the time.

Mr. WAXMAN. Mr. Walgren, do you want to be recognized for any further questions? If you would yield to me, I would like to make a comment on your time in response to the point under discussion.

We already have a law on the books requiring the Department of Agriculture to look after the welfare of animals that are used for research. We are not adequately funding that program. As I see it, this legislation is intended to encourage the private research community to do something on its own and obtain some kind of private sector certification.

In effect we are going to encourage a private sector solution.

By the way, hospitals in this country are accredited by a private organization, JCAH. This legislation would create a similar kind of operation, as I see it, to what is going on for hospitals.

Thank you for allowing me to make that comment.

Mr. WALGREN. I think that is a very important part of the record that we should consider.

I would just like to underscore, perhaps not in the form of a question but in dialog with the other members of the committee that the cost estimates that we have heard are, certainly, extreme approximations not based on any methodology that we would immediately agree upon, as was alluded in Dr. Loew's testimony before.

Just in terms of the Federal cost, assuming we would be able to properly contain the rest of the bill, the Budget Office document that we are discussing indicates that the additional staff at NIH would be five people at a cost of $250,000 a year.

Mr. WAXMAN. Mr. Walgren, I do not want to interrupt you, but I think we are all doing this. We are debating the bill, but we really should hear from the witnesses who have been waiting.

Mr. WALGREN. That is true. If you would just permit me, though, one extra comment and that is, inasmuch as we have apparently a major increased effort to make in the Department of Agriculture inspection system, if we were to make it properly, that extra cost at NIH would be very small in comparison.

You are absolutely correct, Mr. Chairman, and I apologize.

Mr. WAXMAN. Mr. Leland, do you have any further questions?

Mr. LELAND. No further questions.

Mr. WAXMAN. I just want to correct the record on my statement I made here when I drew the analogy to NIH. The correct technical interpretation of the hospital requires that medicare is to meet

Federal standards. JCAH accreditations are deemed to be Federal standards. However, hospitals they may meet Federal standards under other circumstances, which has only a slight relevance to the whole topic of conversation.

I want to thank the three of you very much for your participation. It was very helpful for us to hear your views and question you about the various aspects of this bill.

Thank you.

Mr. WAXMAN. Our final panel today will discuss alternatives to the use of animals in research.

Dr. Michael DeBakey, the chief executive officer of the Baylor College of Medicine at Houston, is well known for his pioneering work in cardiovascular surgery. He is accompanied by Dr. Lawrence Lilienfield, chairman of the Department of Physiology and Biophysics at Georgetown University.

Dr. Andrew Rowan is the director of Laboratory Welfare at the Humane Society of the United States. He is accompanied by Dr. Herbert Rackow, professor emeritus of the Columbia University College of Medicine.

We would like to welcome each of you to our hearing today. Your prepared statements will be made part of the record in full, and we would like to ask you to summarize in around 5 minutes, and we hope to keep within 5 minutes.

Dr. DeBakey would you please start.

STATEMENTS OF MICHAEL E. DEBAKEY, M.D., CHANCELLOR, BAYLOR COLLEGE OF MEDICINE; AND ANDREW ROWAN, M.D., DIRECTOR OF LABORATORY ANIMAL WELFARE, HUMANE SOCIETY OF THE UNITED STATES, ACCOMPANIED BY HERBERT RACKOW, M.D., PROFESSOR EMIRITUS, COLUMBIA UNIVERSITY COLLEGE OF MEDICINE

Dr. DEBAKEY. Thank you very much, Mr. Chairman.

I just want to express my appreciation for the opportunity to appear before this Committee.

Mr. WAXMAN. Please speak into the microphone.

Dr. DEBAKEY. I first want to express my appreciation for the invitation to appear before this Committee and having the opportunity to speak on this bill.

I have submitted a statement for the record which you very kindly referred to. In addition to that, if I may, I would like to submit the statement of the Association of American Medical Colleges. [See p. 134.]

Mr. WAXMAN. Without objection, the statement will be made a part of the record.

Dr. DEBAKEY. Mr. Chairman, in summarizing my own views about this bill, I would simply like to state that I have no concern or objections to the intent of the bill. I do not believe anyone in the scientific community would argue with that. However, I do have some reservations about whether or not this bill would achieve those objectives any more than we can achieve at the present time with our present system.

The process of review and of efforts to establish the main features of standards of humane treatment of animals in laboratories

is regulated by a number of steps through which the budget must go before it ever reaches the animal laboratory. This begins if this project is supported by and has funds, it begins there.

I have had some experience with that, because I have been on study committees at NIH and I have been on councils, and there are two examples right there. If there is any question about the animal resources that are available for that particular project, there is a site visit during which the committee or representatives of the committee will actually go to the site and inspect the animal facilities.

Then, at the local level, in most institutions, there are at least one to three committees that review every project on those same terms. In our own institution, we have three committees that review every research project, not only in terms of the scientific merit of the project but also as in the humane care and treatment of the animals; also, whether or not that particular project requires the use of animals, and what type of animals.

So, my own feeling is that while the intent of this bill is certainly laudable, I personally do not see how it is going to further those objectives that we now have. There are a number of safeguards in that regard, and in relation to the alternatives, since I am a clinician, and my research has been in the clinical discipline, I would like to say that I do not see how the alternatives are going to be any substitute for the kind of research that is now being done where, if it is possible to do so, adequate ethical precautions are being taken. I do not see how you are going to further it by this bill.

Any scientist who is working in any field of science who can find alternate methods to the use of animals is going to do so, because it is usually cheaper. Animals are very costly. And second, if it is possible to achieve the objective of that particular research by that means, then that is his main purpose.

In our own area of research, particularly in the clinical area, there is no substitute by alternative methods to the use of animals if you are going to go from animals to human beings on a particular project. As an illustration, it took us 5 years of animal research on the aortocoronary bypass before we first performed it successfully in 1964.

In my own laboratory, we actually were concerned with the research in animals for 5 years before we decided that we had achieved sufficient efficacy and benefits and results, and lowering the risk to apply it in the human being.

This is true of so many of the pioneers in cardiovascular surgery. This happens in replacement of aortic valves, which began in 1960. In my own case, in the use of dacron grafts for the replacement of arteries, there certainly is no alternative that I can conceive of, no matter how hard I try, to replace the animal experiment before you go to humans to replace their arteries.

I performed the first replacement of a dacron graft in 1953 in a human being after, again, 4 years of research in animals, so we were absolutely certain of the safety. As a matter of fact, you might be amused by the fact that the first grafts that we did, both in animals and man, were homemade. We simply took two sheets of dacron and made a tube out of them by sewing the edges. In

fact, I used my wife's sewing machine to sew the edges together. And that is what we first implanted, both in animals and human beings.

As it was demonstrated that this was successful, we then went on to more sophisticated methods of fabricating, but I personally overall am in accord with this bill and its objectives, but I do not see how it is going to achieve those objectives any better than now, although at considerable cost.

Let me tell you about cost. I heard it stated that it only costs Colorado $1,500. Well, I don't know where you can get secretaries for $1,500. That is one thing. Second, we are fortunate in our own institution. We are actually now planning a new animal facility to upgrade our present facility. I think that is an example of the interesting concern of the scientists in our institution for the best kind of animal facility we can provide.

Second, I think it is also an example of the sort of public concern and the effect of the Animal Welfare Act in enhancing this attitude to upgrade animal facilities, whether or not the threat is there of having your NIH grants not funded unless they meet certain standards.

So, we have safeguards in that regard. We also have the incentive. As I say, we are fortunate in the sense that we are going to spend some $5 million to build a new animal research facility in our institution, not only to upgrade, but to expand it. There are many institutions in this country that are not in that fortunate a position, and would have to depend upon Federal funds for construction grants and renovating grants to do this, and as far as I know right now those virtually do not exist.

So, it is going to cost a considerable amount of money to upgrade many of the research laboratories and animal facilities if you are going to meet the proper standards, and if you are going to have inspection to meet those standards along the lines of this bill, I do not object to that. I think it is desirable to have every institution upgrade their animal facilities in every possible way. I think what we need is money, allocation of funds for this purpose.

I think the series of safeguards we now have established at different levels, from the Federal level down to the local level, are working; certainly, as far as I can tell, they work in our institution. And on the basis of what I know, I think every scientist would agree with the objectives of this bill.

[Dr. DeBakey's prepared statement follows:]

Statement by Michael E. DeBakey, M.D.
Chancellor, Baylor College of Medicine
Houston, Texas

To the Subcommittee on Health and the Environment
Committee on Energy and Commerce
U.S. House of Representatives
December 9, 1982

Mr. Chairman and members of the Subcommittee:

I am Dr. Michael E. DeBakey, Chancellor of Baylor College of Medicine and Chairman of the Department of Surgery.

I appreciate the opportunity to appear before the Subcommittee to express my concern that, in attempting to serve a most honorable intent, the Congress might pass legislation that would seriously impair the mission of medical research.

Certainly I do not disagree with the need for humane treatment of animals used in the research laboratory, or in any other setting. I would also advocate the use of alternate means of research when it is reasonably available.

However, it is my view -- and I think I speak for the overwhelming majority of my colleagues who use animmals for research purposes, as a necessary part of our effort to improve the health and well-being of our citizens -- that additional legislative restraints on animal research is neither required nor desirable.

We already have powerful incentives for appropriate and humane treatment of research animals built into every scientific program that involves their use.

-- The strong guidelines of the National Institutes of Health on the use of animals in research projects are specific and strong. Scientists who violate them risk the loss of their grant support. No reputable scientist is willing to take that risk.

-- Every grant application is subjected to careful, sensitive review when animal research is involved. Any hint of misuse of animals is an established reason for rejecting a grant proposal.

-- The objective of all scientists is to have their work published in reputable scientific journals. The peer reviewers selected by scientific journals to evaluate manuscripts for publication will reject almost automatically any material that hints of cruelty to animals.

-- Scientists must be extremely careful in using animals in experiments. If the animals are not properly cared for and maintained in good health, the validity of the results of their experiments would be subject to question, which would in turn compromise the scientist's professional reputation.

-- Cost is no small consideration. Research animals are expensive. No researcher is going to expend scarce funds by using more animals than absolutely necessary to achieve valid scientific results. Abusing research animals is against the personal financial interest of every scientist.

-- Public opinion is a factor that no institution takes lightly. We are all under the observation of both humane groups and the news media. No institution is willing to take any chance in the treatment of animals that would damage their image with the public.

There are, of course, instances of animal abuses. They will come to the attention of this subcommittee through concerned citizens just as they come to the attention of those of us within the scientific community. When they do, we take the steps necessary to correct them. We do not need additional legislation to force remedial action.

I would submit that a few, isolated instances within the whole of the scientific realm does not justify damaging and costly restrictions that would do vast harm to our nation's medical research effort.

Throughout my adult life, I have worked in the field of cardiovascular surgery. I have seen great progress. Each year tens of thousands of lives are saved by heart bypass operations and other cardiovascular operations. I see many of these cases personally.

I can assure you that without extensive preliminary use of animals during the development of these processes, I would not--nor would other cardiovascular surgeons--have undertaken the surgical procedures necessary to perfect them.

It would have been inconceivable--and completely unethical on its face--to have performed the developmental procedures on human subjects.

Mr. Chairman, I do not take the concerns of humane societies and antivivasectionists lightly, nor do I ridicule their purposes and their efforts. I do not like to see any living being--including animals--suffer. Perhaps, my values may differ somewhat from some. I do not place animal life on the same plane as human life. I do not advocate that we all become vegetarians by mandate. I am concerned--based on my personal experiences in medical research--that many of our victories over the diseases of man, ranging from polio to many forms of cancer, would not have come about without the use of animals in the developmental process.

I don't think it is totally by accident that our advances in combatting cardiovascular disease in this nation in recent decades--assisted in a large measure by animal research--has been so much more rapid than in Great Britain. There are many great British researchers, but their work has been severely restricted because of strong limitations on animal use in experiments.

I do not believe that we want to see that happen to our medical scientists in America.

TITLE I

Now to address some of the specifics in the bill in question. I am particularly concerned about the concept of "alternative methods," as described in Title I. It appears to raise false hopes that can never be fulfilled. Specifically, I have serious reservations about the directive in the report issued by the Committee on Science and Technology that the development of these methods "be singled out as a clear and distinct mission of NIH." To do so, in my opinion, would saddle the NIH with an inappropriate, as well as an impossible mandate.

NIH's mission is biomedical research--testing. In my view the testing should be by the most appropriate, and the most efficient means--within humane bounds--and not restrictive to only narrowly defined procedures.

I believe the directive would be impossible because I am convinced that few, if any, procedures destined for use in man can ever ethically bypass the testing in an animal model. It is simply impossible to simulate in animal culture or in computer models all of the systems of a complex, intact higher organism. While alternative methods may result in a reduced reliance upon animals in the investigative process, they must in reality be considered as adjunct, rather than alternative methods in the vast majority of cases. Recent medical news reports for example, such as the implant of the artificial transplant, the positive emission tomography scanner, and the nuclear magnetic resonance scanner, relied heavily on critical research with animals as models in preparation for human use.

I think I can assure you that if alternate means are available and if they are appropriate and if they are financially feasible that the scientific community will adopt them as a matter of course. They will not need legislation to direct them to do so.

TITLE II

I question the need for the accreditation requirements this bill would impose. The standards of the American Association for Accreditation of Laboratory Animal Care (AAALAC) are certainly desirable in terms of facilities, but they really have little impact on the humane care and treatment of research animals, which depends to a far greater degree on human behavior. I do not believe this can be brought about by national statute. The most effective way to do this is through peer pressure.

I am also concerned about the cost of the proposed requirements, estimated by the Science and Technology Committee at half a billion dollars. It seems to me that this report did not convincingly justify our nation's medical research institutions, many of which are also now struggling to absorb retrenchments in federal expenditures to expend large sums of money without a clear and demonstrated need. This animal research legislation does not, in my view, document this need.

TITLE III

I have doubts about the feasibility, as well as the desirability of actually implementing some of the bill's other requirements.

I am unsure as to the rationale and the benefits to be gained from requiring the employment of a consulting veterinarian in planning cases involving the "direct use of conscious animals." Baylor College of Medicine does employ a veterinarian, of course, to help maintain healthy and humane conditions and treatment for our animals. But I fail to understand how the veterinarian can contribute anything above the medical researcher in the actual experiments.

I also question whether mandating a justification for "anticipated animal distress in terms of the benefits of the research" is even possible. I do not see how anyone can evaluate possible long term benefits and consequences in the early phases of scientific investigation. Such a requirement does not even exist in the statute governing research involving humans.

In summation, Mr. Chairman, speaking as both a scientist and a taxpayer, I am deeply concerned with the vague and subjective nature of the proposed bill and its implications that could severely damage this nation's medical research effort and ultimately the well-being of our society.

I do not argue with the cause of advocating humane treatment of animals. I agree with it. But we must closely safeguard our nations medical research community and assure the scientific community the facilities to develop the cures for diseases that continue to plague man.

I most strongly urge the subcommittee to reject this proposal.

Mr. WAXMAN. Thank you very much, Dr. DeBakey.
Dr. Rowan.

STATEMENT OF ANDREW ROWAN, M.D.

Dr. ROWAN. Thank you very much, Mr. Chairman.

My statement, as you say, is in for the record. I also have two detailed analyses for the information of the committee which I would be happy to turn over at the end of the testimony. I will try to be brief.

I have been working on the issue of alternatives for 7 years, and feel that the concept has merit both for science and for the animal welfare community.

The organization for which I now work supports the entire bill, but I am going to focus just on the alternatives issue. I would also like to state specifically that we recognize that some animal research has produced notable medical advances, and am very flattered to be on the same panel with Dr. DeBakey who, with Dr. Dooley and Dr. Barnard, are people who have made significant advances as a result of animal research.

In the future, I think that we will continue to use animals. What we would like to try and do is to focus on how we can reduce the numbers. We believe that far too many animals are used today in this country and all over the world. Therefore, when we discuss alternatives, what we talk about is methods that can replace the use of animals, methods that can reduce the numbers being used, and methods that can refine the techniques under consideration so as to reduce the amount of suffering. Thus, instead of keeping a primate for 9 months in a restraint chair, perhaps one can develop some other device, such as a jacket holding an implanted catheter to allow the animal to move around freely in the cage, albeit a small cage.

We firmly believe that the development of new technology and techniques is a very important facet of scientific advance. In fact, this has been acknowledged over many years by NIH, in that they have a specific division of research resources that has, as one responsibility, the creation and development of new techniques. Thus, alternatives, that is the development and creation of new techniques which will not involve pain in animals or which will not involve animals at all, is part and parcel of that NIH function.

Those who say that alternatives cannot be supported without diverting resources from necessary animal research should, if they are consistent, also fight against support for laboratory animal resources in the development of animal model techniques since this would also divert resources away from necessary biomedical research. All we are asking for at this point in time is for fair play because animal resources have been extensively supported over the last 20 years, to the tune of hundreds of millions of dollars.

We believe this particular bill is a necessary factor in encouraging NIH and other institutions to support alternatives.

Dr. DeBakey mentioned that the Laboratory Animal Welfare Act has in fact produced many good advances, and has changed the attitude toward the use of animal research. This is generally agreed now, but in 1966, when the Animal Welfare Act was being fought

in these committees, the medical community on the whole opposed it because they felt that they could do the job without legislation. That is the same argument that we are hearing now.

Specific reasons for arguing that the bill is necessary and that we would urge speedy passage are as follows: It will establish a specific and visible Federal program on alternatives, thus giving the concept official sanction and removing it from the limbo it now occupies between NIH and animal welfare advocates. The public, for one, strongly supports the idea of alternatives, but NIH has yet to endorse the concept. This bill will insure that NIH responds to public concern in the same way that the diabetes and nutrition programs have had to be developed via legislative initiative, and yet the bill leaves the actual shape and scope of the program sufficiently flexible so that NIH can satisfy scientific concerns.

This bill will serve to redress the balance of support for biomedical technology. As I have stated, emphasis on animal model resources and technology has been a historic feature of provision of research resources. It is high time that the emphasis was changed and we started to invest in the techniques of the future. The answer to cancer will come from a better understanding of cell growth and cell development, not from experiments on monkeys or mice. The bill will stimulate scientific advance and will improve safety testing by forcing us to evaluate our current techniques and to develop more sensitive, cheaper, and quicker nonanimal methods.

Dr. Donald Kennedy, formerly Commissioner of the FDA and now president of Stanford University, commented in 1978 that:

> Compared with most other contemporary biological technology, animal testing is crude, cumbersome, and expensive. It lacks the speed and finesse of the new techniques now being developed.

We need this particular bill in order to get the national toxicology program focused on appropriate resources and actively interested in the idea of alternatives. They are, in fact, looking at alternatives in carcinogen testing, but we believe this is primarily an economic motive, and that the moral issues have not yet been taken into account.

We do not dispute that research on animals has produced important discoveries, but that certainly does not mean that we have to continue forevermore to use increasing numbers of animals to develop biomedical knowledge. The fact that a horse buggy was once the most efficient means to transport a Congressman from Bethesda to Capitol Hill does not mean that this is still the case. Just as we have ceased to use animals for everyday transport, so modern research technology could be developed until one day we can look back with disdain on today's animal tests.

Thank you very much, Mr. Chairman.

[Testimony resumes on p. 117.]

[Dr. Rowan's prepared statement follows:]

Statement of Dr. Andrew Rowan
Director, Laboratory Animal Welfare
Humane Society of the United States

Good morning Mr. Chairman, members of the subcommittee. My name is Dr. Andrew Rowan. I am here this morning representing The Humane Society of the United States, a national animal-welfare organization with a constituency of 200,000. My credentials to speak on the subject of the use of animals in research are extensive. I am a trained biochemist, having received my doctorate from Oxford University, which I attended on a Rhodes Scholarship. I have devoted the past 7 years to evaluating and promoting the use of non-animal research techniques. I have been invited to speak on this topic at several hundred scientific meetings in Europe, the United Kingdom, and the United States. My published papers on alternatives have resulted in my being awarded the Jorio Rusticelli Prize (Milan) in 1978 and, in 1980, the prestigious Felix Wankel Prize (Munich).

The reduction of pain and suffering endured by animals used in research in this country is a top priority for The HSUS, as is the promotion of research into the development of techniques that would ultimately eliminate the need for laboratory animals altogether.

In support of this goal, The HSUS has, during the last few Congresses, actively supported several pieces of legislation. For example, in the 97th Congress, we supported H.R. 556, a pro-alternatives initiative, and H.R. 4406

which speaks to the issue of the care of animals currently being used in research and experimentation. Congressman Walgren's legislation now before you is, of course, a compromise bill and it is not as strong as we would like it to be. Nevertheless, we believe that H.R. 6928 contains important elements which are worth supporting. We thus are calling for the swift passage and enactment of H.R. 6928.

There is no question that the time for this legislation has arrived. Thanks to the hard work of Congressman Walgren and his subcommittee staff, this legislation now has some 65 cosponsors, not to mention tremendous public support.

The use of animals in research in this country is a major industry. Between $9 and $10 billion is spent every year in the U.S. alone on biomedical research activities, approximately 45 percent of which involved research or testing on animals. The number of animals consumed every year by the biomedical research machine is enormous. Despite contentions from the scientific community that the number of animals used annually is approximately 20 million, our best estimates indicate that the actual number of animals that give their lives every year for science and supposed human benefit is more than three times that (See Appendix A). Most of these animals are mice and rats (which, by the way, currently have no protection under the Animal Welfare Act), but large numbers of dogs, cats,

primates, guinea pigs, rabbits and birds also suffer pain and ultimately death every year in the name of scientific progress.

Science has usually argued that these animals do not suffer because anesthetics are used. However, in too many cases, this is simply not true. Many millions of animals suffer horribly in toxicity testing, in screening for possible new drugs, in infectious disease research, in behavioral studies, and in countless other types of experiments where the use of anesthetics or painkillers would "interfere" with the research. The legislation now before you would ameliorate at least some of that suffering, not by limiting scientists in what they may do, but in requring them to justify the need to subject sentient creatures to pain and suffering.

It cannot be denied that the public wants to see this legislation enacted. There has always been opposition to the use of animals in research and each Congress has received many thousands of letters from a small, but vocal constituency. Congress has traditionally, tended to ignore this element of the public. However, public disquiet about the use of animals in cosmetics research, in expensive and useless toxicity tests, in weapons research and many other types of painful experimentation, has grown substantially in the last decade. In the 1950's and 60's, the public overwhelmingly supported the use of animals in research.

A 1949 survey conducted by the University of Chicago found that 85 percent of those polled favored the use of animals in medical teaching and research. Constrast to that a poll conducted just last year, which found that 63 percent of the respondents now oppose even medical research using animals. The percentage of those disapproving of cosmetics testing on animals was even higher (see Appendix B). The public is demanding, with ever increasing intensity and effect, that specific and very visible programs be put into effect to protect laboratory animals from needless pain and suffering and to reduce their numbers used annually.

We are not, however, urging enactment of this legislation only because the public is demanding it. Sections of this legislation, specifically those which deal with the development of non-animal research techniques, should, in the long run, actually improve science rather than hinder it, as some here today will claim. I am prepared today to show that it IS possible to develop alternatives without sacrificing current scientific momentum. The development of alternatives to animals is imperative not only from an ethical viewpoint, but also could advance human health and safety more effectively and economically than the use of laboratory animals.

There are many provisions of this bill that The HSUS actively supports, including: -

Title I a) the authorization which allows the Secretary of HHS to make awards specifically for alternatives.

b) the directive to evaluate and validate alternatives;

c) the establishment of an Advisory Panel on alternatives;

d) the directive that the Secretary of HHS initiate interagency co-ordination on alternatives;

e) the directive to ensure efficient data storage and retrieval so as to reduce animal use;

f) the directive to the National Toxicology Program to increase its effort on alternatives by a significant amount; and

g) the directive to the Secretary of HHS to report regularly on progress of alternatives.

Title II h) the requirement that institutions receiving federal funds establish an Animal Studies Committee, with one public member charged with representing the interests of the animal, to inspect facilities on a regular basis, to review ongoing research, to establish training courses in alternatives and humane experimental techniques, and to be legally responsible for animal research in each institution;

i) the establishment of a clearinghouse for information on these techniques;

Title III j) the requirement that grant applications include a justification of anticipated animal distress in terms of the benefits of the research (The HSUS scientific division, in a study of 575 funded grant proposals in 1976, found that most did not contain sufficient information to allow peer review committees to make a proper judgement on this issue).

In the remainder of my testimony, I will concentrate on the reasons why we feel that some specific legislation is needed on alternatives.

ALTERNATIVES

The concept of alternatives (or non-animal methodology as it is called in H.R. 6928) covers many different techniques, including cell and organ culture in test tubes, computer and mathematical models, microbiological systems, and epidemiological and clinical studies. I have always used the term to refer to the three R's of Replacement, Reduction, and Refinement. That is, it covers not only any technique which can replace the use of live animals altogether, but also those techniques which either reduce the number of live animals required for a particular study, or which reduce the amount

of suffering which the animals undergo. But it is more than just a collection of new techniques--it represents an entirely new approach to research in which a high priority is given to reducing the use of suffering of laboratory animals in a wide variety of ways. As human research and related ethical questions came under close scrutiny in the '70's, so the '80's will be the decade for reassessing the ethics of animal research and testing.

As it turns out, economics is on the side of ethics in this instance. Alternative techniques are, as a rule, quicker and cheaper than animal models. For example, an animal test to detect a carcinogen takes three and a half years to complete and costs half a million dollars. A battery of non-animal tests, which are just as effective in identifying carcinogens according to Dr. David Brusick of Litton Bionetics, takes three months and costs only $25,000. The cost and time savings in this instance are higher than average, but they provide a flavor of what might be achieved, especially in the field of safety testing, by switching to a greater dependence on alternatives.

Already, public pressure in other countries is resulting in increasing emphasis being placed on the development of alternatives. For instance:

-- In Sweden, the government has allocated approximately $100,000 per year to support specific research into alternatives.

-- In Holland, the Dutch Minister of Health announced at a laboratory animal science conference in 1979 that his government would seek explicit support among their European partners for the promotion of alternatives.

-- Even as we sit here today, The Council of Europe Parliament is debating the question of research on animals and especially the concept of alternatives.

-- In England, a committee of toxicologists has recommended that there should be specific support for alternatives research and has raised half a million dollars from industry to initiate four projects.

-- Another committee of toxicologists, this time in Canada, has recommended that their government should fund research with the specific aim of developing alternatives to animal tests.

These types of activities are not confined to other nations. Here in the U.S., a number of cosmetic companies have set aside more than $2 million to support alternatives research. The Pharmaceutical Manufacturers Association has publicly criticized the LD50 test, which is also under attack from over 400 animal welfare groups, and has indicated that member companies could substantially reduce their use of animals in drug testing if the regulatory agencies would permit it. Science, the American science journal, carried an article on alternatives that indicated the concept had considerable potential (see appendix c), especially in the safety testing of chemicals. In biomeddcal research, as

opposed to safety testing, federal funding groups have also taken a few tentative steps to promote alternative models. The Department of Defence states that researchers who use animals must consider alternatives in planning their research. At the National Institutes of Health, the Division of Research Resources has allocated less than one percent of its budget to evaluate biomedical research models, including some models that would qualify as alternatives.

Given the above activity, some might ask why we even need a bill to promote alternatives. In fact, much of the scientific criticism of Title I is based on arguments that alternatives have been developed in the past by scientists who recognized their economic and scientific advantages (TRUE), and that they will not be developed any faster in the future, even if we set up specific programs to promote alternatives (FALSE). We believe this bill is necessary for the following reasons.

1. IT WILL ESTABLISH A SPECIFIC AND VISIBLE FEDERAL PROGRAM ON ALTERNATIVES THUS GIVING THE CONCEPT OFFICIAL SANCTION AND REMOVING IT FROM THE LIMBO IT NOW OCCUPIES BETWEEN NIH AND ANIMAL WELFARE ADVOCATES.

The public strongly supports the idea of alternatives but NIH, for one, has yet to endorse the concept despite the fact that it functions on public tax money and only at

"the pleasure of the people". This bill will ensure that NIH responds to public concern (in the same way that the diabetes and nutrition programs had to be developed via legislative initiative) and yet leaves the actual shape and scope of the program sufficiently flexible so that NIH can satisfy its scientific concerns as well.

2. THIS BILL WILL SERVE TO REDRESS THE BALANCE OF SUPPORT FOR BIOMEDICAL TECHNOLOGY.

For the past twenty years, NIH has given hundreds of millions of dollars specifically to support laboratory animal resources and the development of animal models. Powerful interest groups have grown up to ensure that this level of support continues. For example, twenty years ago primate researchers were accorded the status of Most Favored Scientists when seven primate centers were established to develop our knowledge about primate breeding and husbandry in captivity. Since then the program has received well over one hundred million dollars in spite of numerous critical reviews citing its inadequacies. Over the same period, support for cell culture resources and the development of cell culture technology has been very meager (no more than a few million dollars). It is high time that the emphasis was changed and that we start to invest in the techniques of the future. The answer to cancer will come from a better understanding of cell growth and cell development, not from experiments on monkeys or mice.

3. THE BILL WILL STIMULATE SCIENTIFIC ADVANCE AND WILL IMPROVE SAFETY TESTING BY FORCING US TO EVALUATE OUR CURRENT TECHNIQUES AND TO DEVELOP MORE SENSITIVE CHEAPER AND QUICKER NON-ANIMAL METHODS.

There has already been some recognition of the importance of technique development and resource support. The Division of Research Resources was established with this responsibility. Nobel prizes have been awarded to researchers who have developed powerful new techniques which have opened up exciting new areas of research - e.g. nucleic acid sequencing (genetic engineering) and radio-immunoassay (endocrinology and immunology).

Safety testing is an area where the development of new ideas and new techniques could be particularly startling in relation to reduced costs, shorter time scales and improved hazard evaluation. In addition, the ethical issue raised by toxicity testing on animals is now being recognized as a growing problem as pressure has served to highlight a number of areas where regulatory authorities and research managers have stayed with the status quo (and continuing mass slaughter of animals) rather than spend time evaluating the need for various tests or support research into the development of more efficient tests. For example, none of the regulatory changes in the Draize test nor the funding of new research projects seeking a non-animal alternative test for irritancy would have happened if it had not been for the intense public pressure mobilized by the animal welfare movement in 1980.

The LD50 is another test which is long overdue for the scrap heap but once again, it appears that it will take a concerted animal welfare campaign to force regulatory scientists to confront the modern age. Dr. Donald Kennedy, a former commissioner of the FDA and now President of Stanford University commented in 1978 that "compared with most other contemporary biological technology, it (animal testing) is crude cumbersome and expensive. It lacks the speed and finesse of the new techniques now being developed..." (speech to Writer's Seminar, American Cancer Society, Houston, Apirl 1, 1978).

We need this bill, especially the paragraph directing the National Toxicology Program (NTP) to develop a substantial research program seeking alternative tests, to break free of "crude, cumbersome and expensive" animal tests. The NTP has so far shown very little interest in alternatives. This bill is needed to make them recognize the extent of public concern about animal testing and their desire to see major initiatives on alternatives.

Conclusion

We do not dispute that research on animals has produced important discoveries but that certainly does not mean that we have to continue, for evermore, to use increasing numbers of animals to develop biomedical knowledge. The fact that a horse buggy was once the most efficient means to transport

a Congressman from Bethesda to Capitol Hill does not mean that this is still the case. Just as we have ceased to use animals for everyday transport, so modern research technology could be developed until one day we can look back with disdain on the imprecision of animal tests.

That day will come all the sooner with the passage of this legislation. The public wants alternatives to receive the imprimatur of approval of biomedical funding agencies and such approval could lead to initiatives which would address both the need for scientific advance and the concern of the animal welfare movement and its supporters.

The animal welfare movement has been called a sleeping giant. This issue has stimulated the giant to begin to stir. Only time will tell if it will fully awaken.

APPENDIX A: NUMBERS OF LABORATORY ANIMALS

There are many conflicting reports on how many laboratory animals are used every year. We estimate that approximately 60-80 million animals are used annually but others claim that the figure is far lower. Our best estimates for number of animals used annually are as follows: -

	Low	High
Mice	40,000,000	50,000,000
Rats	10,000,000	18,000,000
Hamsters	600,000	1,400,000
Guinea-pigs	750,000	1,500,000
Rabbits	600,000	1,200,000
Dogs	200,000	400,000
Cats	75,000	115,000
Primates	25,000	35,000
Birds	1,100,000	3,000,000
Amphibians	3,000,000	5,000,000
TOTALS	56,250,000	80,650,000

We base our estimates on the following data.

a) In 1965, W. B. Saunders and Company, a group of economic consultants, conducted a market survey of the current and projected demand for small laboratory animals in the USA. Their figures were based a) on NIH use and the

determination of NIH use as a percentage of the total demand and b) on extrapolation from the sales figures from a known sample of laboratory animal breeders. There was less than a two percent difference between the two totals and their final tables are given below. (Information Lab. Animals for Research (1966) 9(3): 10).

	1965	1970 (projections)
Mice	36.84 m.	59.56 m.
Rats	15.66 m.	25.32 m.
Guinea pigs	2.52 m.	4.07 m.
Hamsters	3.30 m.	5.34 m.
Rabbits	1.56 m.	2.52 m.
Exotics	0.12 m.	0.19 m.
	60.00 m.	97.00 m.

The 1965 estimate is in reasonable agreement with a series of surveys carried out by the Institute for Laboratory Animal Resources between 1965 and 1971 which indicated that at least 55 million laboratory animals were used annually.

b) According to laboratory animal breeders, the demand for laboratory animals was relatively stable between 1970 and 1975 and then grew again in the latter half of the decade.

c) A 1981 market analysis of annual sales of laboratory animals (Alex Brown and Sons) indicated that Charles River

Breeding Laboratories controlled about 20% of the domestic market and that they sold 12-14 million rodents every year in the United States. Jackson Laboratories, which reportedly sells 2 million rodents annually, was estimated to control about 3% of the market. Extrapolating these figures leads one to the conclusion that the market for laboratory rodents in the United States is about 60 million annually.

d) In 1979, it was reported that National Cancer Institute (NCI) research programs use approximately 6.5 million rodents annually (Hearings before a Subcommittee of the Committee on Appropriations, House of Representatives, 96th Congress, First Session, Part 4, pg 486). Since the NCI accounts for approximately 10% of national outlays for biomedical research, it can be inferred that the nation uses approximately 65 million laboratory rodents annually.

e) Other estimates of laboratory animal use are similar to our own. In fact, the only estimate that is out of step comes from the 1978 survey conducted by the Institute for Laboratory Animal Resources which reported that only 20 million animals are used every year. It is, at the moment, unclear why the ILAR survey should have produced such a low figure, even given that they had only a 50% return of questionnaires.

Conclusion

We are, therefore, satisfied that the best estimate of annual laboratory animal use in the United States falls in between 60 and 80 million. We are prepared to accept that this figure has now stabilized and is possibly even declining. We are, however, of the opinion that it is far too high and that only modest changes of testing regulations and research approach could reduce these figures substantially.

APPENDIX B: PUBLIC ATTITUDES TO ANIMAL RESEARCH AND TESTING

In the forties, fifties, and sixties there was widespread public support for research. For example, in 1949, the University of Chicago commissioned an opinion poll which found that 85% of the population favored the use of animals in medical research and teaching with only 8% opposed. In 1951 in Los Angeles, even though antivivisection arguments were actively promoted by the Los Angeles Times, a 1951 public referendum on the use of dogs in research favored the researchers by 3 to 2. Today, the results would probably be reversed. A 1979 poll by the Detroit Free Press indicated that 76% of the respondents were strongly in favor of research support for alternatives.

Recently, Glamour magazine (December, 1981) conducted a poll of its readers. While it was hardly a controlled and scientific assessment of the public's attitude, the results were still very surprising. For example, 63% of those responding said we should NOT continue to use animals in MEDICAL research. An overwhelming 84% said we should not use animals in cosmetic testing and 59% said they would be willing to use a drug even though the lack of animal testing would mean that it might not be as safe.

Obviously we do not wish to read too much into such a media survey but these results are supported by a more systematic survey of 302 university undergraduates. The students were prepared to approve the painless killing of toads, mice and monkeys for drug testing but a majority disapproved of all other research practices (see Table).

Table	% Approved	Neutral	% Disapproved
Killing animals PAINLESSLY to test a new drug			
Toads	56	30	15
Mice	55	28	17
Monkeys	37	29	34
Dogs	32	23	45
Killing animals PAINLESSLY for non-medical research			
Toads	21	28	51
Mice	24	30	46
Monkeys	9	17	74
Dogs	10	15	76
Killing animals PAINFULLY for drug testing			
Toads	19	22	59
Mice	18	19	63
Monkeys	12	13	76
Dogs	11	11	78
Killing animals PAINFULLY for non-medical research			
Toads	5	11	84
Mice	7	12	81
Monkeys	2	6	92
Dogs	2	7	91

Results from Int. J. Study Animal Problems 3: 42-49 (1982).

Many animals (at least 20 million in the USA every year) suffer before they die in research and testing on drugs, food additives, toiletries, cosmetics and many other chemicals. The above survey indicates that a sizable proportion of the public with university degrees would disapprove of the use of animals in painful research and testing if they were conscious that it was happening. Certainly, when the public were told about the testing of cosmetics in rabbit eyes, they protested so strongly that both the cosmetic industry and the government agencies that regulated the industry were forced to take action to ameliorate the situation.

Appendix C

New Focus on Replacing Animals in the Lab

Animal welfare movement is raising consciousness, but science and economics supply the main impetus for change

In the past few years the animal welfare movement has undergone both philosophical and scientific bolstering. Animal activists have long been concerned about the use of animals in scientific research, but now, instead of only attacking allegedly inhumane experiments, they are actively promoting the development of "alternatives" to the use of animals in research.

This concern has found expression in the introduction of a bill in Congress (HR 556) which calls for the establishment of a Center for Alternative Research in the National Institutes of Health (NIH) and the diversion of up to 50 percent of all appropriations for animal-related research to research using alternatives.

Members of the House Science and Technology Committee are now trying to design a more moderate measure. H.R. 556 might sound promising if the failure of scientists to shift their work massively away from the use of whole animals (usually meaning vertebrates) were owing to a combination of inertia and lack of funds. The fact is, however, as was made clear at congressional hearings in October, a massive shift away from the use of animals in research will not be possible in the foreseeable future. The technology is not just sitting around waiting to be deployed. Rather, much more basic research using animals will be necessary before major reductions are possible.

Just what are "alternatives"? H.R. 556 defines them as including "mathematical models, isolated organs, tissue and cell cultures, chemical assays, anthropomorphic dummies, simulated tissues and body fluids, mechanical models, computer simulations or lower organisms." Broadly speaking, gene splicing and work with hybridomas—which enables the creation of large quantities of antibodies in vitro—qualify as alternatives to animals. So do various newly developed technologies, such as positron emission tomography and nuclear magnetic resonance, which permit noninvasive scanning of an organism.

Many animal welfare people talk rather glibly about "alternatives" as though one-to-one substitutions of nonanimal for animal tests could be made in the foreseeable future. But others prefer a broader definition covering the "three R's"—replacement, reduction (of animals), and refinement (of tests). Some scientists balk altogether at the idea that alternatives can "replace" animals, since the only genuine substitution for a whole animal is another whole animal. They prefer to refer to nonanimal research methods as "adjuncts" to animal tests.

In fact, over the past 5 years or so, there has been considerable movement toward adoption of nonwhole-animal assays in toxicity testing—specifically tests for mutagenicity and carcinogenicity (teratogenicity, which is usually mentioned in conjunction with these, is still not amenable to detection without using live animals). One of the driving forces was the passage in 1976 of the Toxic Substances Control Act (TSCA) which, when fully implemented, will mandate premarket toxicity testing of all new industrial chemicals. With hundreds of major new chemicals entering the market each year, scientists are under great pressure to use available facilities as efficiently as possible; in vitro screening techniques offer valuable information on which chemicals are potential hazards and therefore candidates for animal screening.

Another, though lesser, impetus for reducing animal use is supplied by developments in basic biomedical research. Rapid strides in molecular and cell biology have pushed the frontiers of biology closer and closer to fundamental mysteries—to the rules that govern all life—so that many basic questions about cell behavior are best addressed through isolation of the simplest systems possible.

Despite all the options cited by animal activists—ranging from elimination of duplicative research to the substitution of "lower" animals for vertebrates—there are basically two major approaches that show promise for reducing animal use. One is generally referred to as short-term tests, involving the cultivation of living material in culture; the other is mathematical modeling.

Short-term tests have become vital to toxicology testing, thanks to TSCA and the government's concern with environmental toxins as well as the high cost of animal toxicity studies. Toxicology testing has become a huge business. About 63,000 chemicals are in common use, some 48,000 of them in commercially significant amounts, according to the National Toxicology Program of the National Institutes of Health (NIH), which tests selected chemicals. More than 500 new ones are introduced each year. Only about 6000 had been tested for carcinogenicity by 1978, according to the Environmental Protection Agency. The nation has the capacity to test only about 300 a year. It costs about $500,000 to subject rats and mice to a lifetime cancer study. A total toxicological work-up, including such things as special tests for eye and skin toxicity, can run as high as $2.5 million.

Short-term tests are most useful in determining mutagenicity (changes in DNA), which is usually an indicator of carcinogenicity. The Ames test, developed in 1971, is by far the best known of the in vitro assays and is now used in some 2000 laboratories around the country. It involves application of a chemical to a preparation of *Salmonella* bacteria, with rat liver extract added to metabolize the compound. The Ames test is about 80 percent reliable in determining mutagenicity (since it is more sensitive than an animal assay it usually errs on the side of false positives).

In the future, scientists expect that batteries of short-term tests will reduce the need for many in vivo toxicity tests. David Brusick of Litton Bionetics believes "we should be able to completely replace the whole-animal [toxicity] bioassay with an appropriate set of short-term tests coupled with metabolic studies in mammals."

At the Food and Drug Administration (FDA), four mutagenicity tests are now allowed to substitute for preliminary animal cancer screens of drugs administered to food animals. And the agency is considering allowing manufacturers of human food additives to substitute several overlapping in vitro tests for an animal carcinogenicity assay on "low concern" additives. A manufacturer would then use some or all of the following: an Ames test, a *Drosophila* test (looking for mutations in multiple generations of fruit flies), a test looking for an unscheduled DNA synthesis in cells in culture, a test for a point mutation in a mammalian cell culture, and a mammalian cell transformation test. If results are negative, about $450,000 could be saved

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by bypassing an in vivo carcinogenicity study.

Although tests for genetic toxicity offer the only widely used shortcut in toxicological testing, others are on the horizon. Chick embryos, for example, may prove a cheaper, more convenient and less wasteful way to do some kinds of neurotoxicity testing. At an NIH symposium last February,* Stata Norton of the University of Kansas reported that she was able to produce the same effects from morphine injections in chick embryos as in baby rats. She suggested that the chick embryo is "a simpler system which nevertheless retains some of the complexity of the mammalian nervous system" and thus was able to provide some information that ordinarily is gained from mammals.

Cells in culture are also used in screening for new pharmaceuticals. The National Cancer Institute (NCI) is starting a $1-million-a-year program to test possible anticancer drugs with an assay on cultures of human cancer cells. Currently, the NCI drug testing program uses two banks of mouse experiments in the early stages of determining whether a new drug shows promise in anticancer activity. The human cancer cell assay will be used as a supplement, and if it does as well in predicting anticancer activity as rodent experiments, it may ultimately replace them. Bristol-Myers recently announced a similar project, in which new drugs are being tested on cultured cells from individual human cancers. The hope is that this will be a more effective way of matching chemotherapy to particular types of cancers than is offered by mouse assays.

Enormous strides in cell and organ culture have been made in recent years with the result that scientists theoretically possess the know-how to keep any type of cell culture alive in a medium for an extended period of time without their regressing to a more primitive state (as noncancerous cells are wont to do). Most cell culturing is done in the service of basic research and has not been exploited as much as it could be in toxicity testing, says Roland Nardone of Catholic University.

But currently, for the first time, several groups are involved in applied research, including the use of cell cultures, to seek nonwhole-animal bioassays to replace the notorious Draize test. The Draize test is an ocular toxicity test in which substances are placed in the eyes of rabbits. It has for several years been the target of a coalition of some 400 animal welfare groups who selected it as a cause with public appeal. Not only does it involve hurting rabbits, but it is widely used in testing of nonessential substances, namely, cosmetics. The Draize coalition has been remarkably successful at turning public pressure onto cosmetic companies, who have capitulated recently by awarding substantial sums for research on nonanimal substitutes. Thus, within the past year, four different institutions† have begun research programs. The largest is at Johns Hopkins University which got $1 million from the cosmetics industry to set up a Center for Alternatives to Animal Testing. Its head, Alan Goldberg, says the center is unusual in that its research programs—both intramural and extramural—are being designed to run the gamut from fundamental research to applications. Goldberg says they are now looking for proposals to investigate cell mechanisms, particularly how cells and tissues respond to foreign challenges.

At Rockefeller University a group headed by Dennis Stark will also be doing basic research, with particular emphasis on developing data on the inflammatory response. Stark doesn't have any idea what kinds of tests his group will come up with but speculates that in order to replace the Draize test a bank of perhaps ten tests will have to be developed. He envisages separate tests for the various parts of the eye that might be affected as well as for the inflammatory response, effects of treatment, duration of damage, and so forth.

Joseph Leighton at the Medical College of Pennsylvania, who believes that use of the Draize test can ultimately be reduced by 90 percent, is working with chick embryos. He says the vascular membrane covering the egg, called the chorioallantoic membrane, has complicated features that confer some of the benefit of working with a whole animal. Finally, at Tufts University, William Douglas is experimenting with cultures of human corneal cells.

At Johnson and Johnson Baby Products, John McCormack reported at the NIH February meeting, yet another in vitro ocular toxicity test has been developed, this one using mast cells from rat peritoneal tissue. This test, used with water-soluble surface-active substances such as shampoos, involves measuring the release of radioactively labeled serotonin by the mast cells. Serotonin is liberated in conjunction with histamine which in turn is related to inflammation. McCormack says the test has high correlation with in vivo results, and one rat peritoneum supplies findings that would require 48 whole animals in an in vivo study.

Far more knowledge gained from basic research will be required before any quantum gains can be made in replacing animals. As one investigator said, "we still don't even know how a single bacterial cell works," and until we do, it is difficult to extrapolate from cell activity in a tissue or cell culture to the same activity in a whole animal.

Aside from short-term tests, mathematical modeling is the other area that shows greatest promise for the eventual reduction of animal use. The newest development, ascribed chiefly to the work of Corwin Hansch of Pomona College in California, is called quantitative structure activity relationship analysis. This approach, using computers, occupies an even more preliminary position than in vitro tests in the hierarchy of testing that culminates in experiments with human subjects. It is being used as a method to make preliminary identification of both toxicity and efficacy of compounds. It is based on mathematical expressions of the relationship between a compound's chemical structure and its activity. Hansch explains that conversion of structural characteristics into numbers allows for much more precision than do pictures of molecules; it also tells the investigator which differences between two compounds are significant and which trivial. Structure activity analysis relies on having a large data base containing the chemical structures of known molecules, and then comparing various molecular fragments or "keys" with those of the known chemicals.

The NCI is using structure activity analysis to screen the thousands of new chemicals sent in each year for antitumor activity. The Drug Synthesis and Chemistry Branch of the NCI's Developmental Therapeutics Program acquires samples of some 20,000 new compounds each year from its worldwide network of sources, according to Louis Hodes. The molecular structure of each is put through a computer and compared with those in their training set (data base) of 55,000 known compounds. The computer surveys each molecule, atom by atom, looking for two things: uniqueness and activity. Compounds that show activity but are very similar to antitumor drugs already available are discarded; anything with an unusual structure or that has keys in common with compounds of known activity is subjected to chemical analysis and, if approved, is moved to the prescreening stage, which involves testing it on a particular type of mouse leukemia. About half the new chemicals are eliminated before they get to the mouse screen, which means the efficiency of the animal tests has doubled over the 5 years that the present screening program has been in place.

There is also growing use of mathematical models for parts of whole systems such as the cardiovascular system or the immune system. But they require enormous amounts of data—all acquired from animal experimentation—in order to be useful. Arthur Guyton of the University of Mississippi, for example, reported at the NIH meeting that mathematical modeling of high blood pressure shows that increased peripheral resistance in blood vessels cannot cause permanent hypertension—a finding that runs counter to what is taught in most medical schools. Guyton says modeling can make animal research more efficient, but it can also lead to increased numbers of animal bioassays because it raises so many new questions.

Some people believe, however, that increased use of mathematical models can lead to reduced animal use. Charles DeLisi, mathematical biologist at NCI, cites a mathematical formulation involving interactions between tumor cells and immune cells which predicts that the immune system can sometimes stimulate tumor growth. DeLisi thinks mathematics is underutilized by biologists who are often unaware when questions arise that are good candidates for mathematial solutions.

The more one learns about these new research methodologies, the clearer it becomes that very few can be realized as direct substitutes for animal bioassays. Rather, they are opening up new realms of investigation which will in many cases lead to reduction of animal use and refinement of animal experiments.

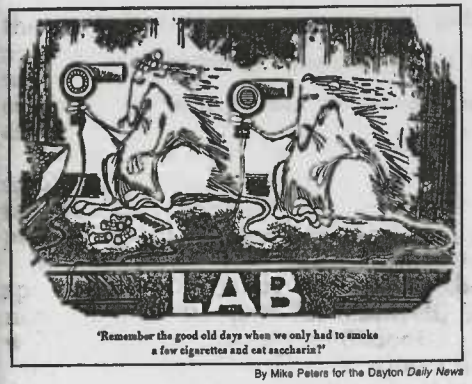
There is already evidence that lab animal use is decreasing. The National Academy of Sciences (NAS) reported in 1978 that use of research animals had gone down by 40 percent in the prior decade, from about 33 million to about 20 million among laboratories polled. Many people dispute these figures, contending that annual consumption of research animals is more like 60 million. Either way, most of the decline is attributable to the rising costs of animal purchase and care and an increase in chronic toxicity testing (which reduces turnover), according to the NAS. The reduction of animal use in education is also a significant factor.

There is considerable debate over the best use of short-term and other nonanimal tests, which inevitably includes debate about animal tests. Animal welfare people, for example, are likely to be much more skeptical of the value of animal tests—and the extrapolation of their results to humans—than are animal toxicologists. Interestingly, the thalidomide disaster is cited by both camps, with some people claiming not enough animal testing was done, and others saying it is a perfect example of their inadequacy. Thalidomide had been tested on rodents and rabbits, but the teratogenic effect showed up only in one strain of rabbit.

Questions about validity of in vivo tests relate to growing criticism of the LD_{50}, which is the next target of the anti-Draize test coalition. The LD_{50}, developed in 1927, was originally intended as an index of drug toxicity. Now it is required for any substance—food additive, drug, household product, or industrial chemical—to which humans will be widely or heavily exposed. The test has been criticized as a crude one whose only end point is death. It is said to be of marginal usefulness in most cases because so many factors influence the outcome and extrapolation of the results to humans is questionable. Furthermore, with a substance of minimal toxicity, test populations have to be fed so much of it to get results that they may die from secondary effects unrelated to toxicity.

Government regulations are a significant obstacle to the adoption of safety tests that don't require animals, and chemical manufacturers are reluctant to take the initiative in developing nonanimal tests because of product liability fears. Thus, the most immediate gains stand to be made in the area of test validation. There are hundreds of in vitro tests available, but none are going to be widely used, or accepted for regulatory purposes, until they have been shown to be at least as sensitive as an animal system. In the meantime, there have been moves to reduce unnecessary duplication of tests by standardizing some of the ones required by four regulatory agencies: the Environmental Protection Agency, the Food and Drug Administration (FDA), the Consumer Product Safety Commission, and the Occupational Safety and Health Administration. An Interagency Regulatory Liaison Group (set up under President Carter and now defunct), headed by Victor Morgenroth of the FDA, has issued guidelines for four types of tests: acute dermal toxicity, acute oral toxicity, teratogenicity, and acute eye irritation. If the group's recommendations are heeded they could result in a significant drop in Draize tests, as the eye irritation guidelines say "substances known to be corrosive may be assumed to be eye irritants and should not be tested in the eye."

An accumulation of small changes is probably going to have more effect on the adoption of "alternatives" than a big new federal initiative. History would seem to indicate that animals are naturally replaced when scientists discover the mechanism of the purpose for which



'Remember the good old days when we only had to smoke a few cigarettes and eat saccharin?'

By Mike Peters for the Dayton *Daily News*

*Trends in Bioassay Methodology: In vivo, in vitro and Mathematical Approaches, organized by William Raub, director of extramural research at NIH.

†Tufts University has a grant of $176,000 from the American Fund for Alternatives to Animal Research; the Medical College of Pennsylvania has received $100,000 from the New England Antivivisection Society; Rockefeller University has a $750,000 grant from Revlon; Johns Hopkins has received $1 million from the Cosmetics, Toiletry and Fragrances Association and an additional $300,000 from Bristol-Myers.

they were used. Canaries are no longer employed to monitor the air in mines; rabbits (and later frogs) are no longer needed to discover pregnancy. As Donald Kennedy, former FDA head, said recently, "compared with most other contemporary biological techniques, animal testing is crude, cumbersome and expensive." But there is still nothing like an animal. To eliminate animals in testing, claims Hansch, "you would have to totally understand life in all its detail."

The extent to which the animal welfare movement is hastening the development of alternative methods is not clear. Certainly, the movement can claim responsibility for the new initiatives aimed at replacing the Draize test. But otherwise, it is far less of an influence than economic or scientific imperatives.

The movement is unquestionably affecting how many scientists view their work. Some see this as consciousness-raising for scientists who work with animals—just as physicists developed a new awareness about the implications of their work after the bomb, and more recently clinicians developed a new sensitivity toward the rights of human subjects. What frightens some scientists is that the current movement is gaining added force from America's streak of anti-intellectualism, which lends a flavor to the extreme wing of the animal rights movement reminiscent of right-to-life and creationist zealotry.

Leaving out the extremists on both sides of the question, scientists and animal welfare people do not appear to be much in conflict. Franklin M. Loew of Johns Hopkins University, head of the NAS laboratory animal group, believes there is really only a difference in priorities: the animal people see reduction of animal use as a desirable goal in itself; while to scientists, the goal is secondary to that of doing good science. There is greater disagreement over means, with one group pressing for more money while the other contends that development of alternatives is progressing as fast as the science will allow.

There are few who believe that all animals can some day be eliminated from research. In many areas, including disease modeling, experimental surgery, and many behavioral studies, the only substitute for an animal would be a human being. Otherwise it is difficult to predict the future since both the science and the ethics are in flux. Says William Raub of NIH: "There is the possibility that 10 years from now our current views of the ethics and morality of research will be labeled as being biologically naive."—CONSTANCE HOLDEN

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Mr. WAXMAN. Thank you very much, Dr. Rowan.

You suggest that nonanimal research would be both better and cheaper. Could you elaborate on that?

Dr. ROWAN. Well, in the carcinogen testing that I referred to briefly, the animal test requires 3 to 3½ years to complete, and half a million dollars of money to support it. A battery of nonanimal tests requires about 3 months to complete and $25,000. They are both, as far as some individuals in the scientific community are concerned, as efficient in detecting carcinogens.

Dr. Dave Brusick, who testified before the Science and Technology Committee, mentioned that fact. He is one of those who feels that the detection of carcinogens via in vitro tests is equivalent to animal detection systems.

Additionally, as I said, research advance has always depended on the development of new technology. Many Nobel prizes have been awarded specifically for the development of new techniques, and we feel that it is not at variance with the established practice and established funding practices for biomedical research to focus specifically on those new techniques.

What we are asking is that NIH and the other Federal funding agencies take into account public concern about the use of animals, that they try, insofar as is possible, to find techniques that will replace and/or eliminate the need for animal research.

Mr. WAXMAN. Dr. DeBakey, I would be interested in your response to the question of whether the scientists generally look for nonanimal techniques for research, particularly if such techniques will be cheaper and more efficient.

Dr. DEBAKEY. Yes. That is what I do not understand. I do not understand the need for a bill to do this.

Mr. WAXMAN. Sometimes people do not look at these kinds of questions unless they are pushed. The animals are readily there. Scientists will use animals. But if you push them to do something else, they will look at the other alternatives.

Dr. DEBAKEY. I do not think that that is quite right, Mr. Chairman. I think that the scientists are interested in achieving certain objectives in the scientific work, and if the method is available for them in this regard, they will use nonanimal element, but the unfortunate thing about it is that in many instances, in many forms of research, the nonanimal model simply cannot achieve that objective.

Now, if it is desired to try more research on nonanimal models, then all that is needed is more money for that purpose. You do not have to have a bill for that purpose. It is very easy to express the intent of Congress in that regard by placing within the appropriations report a line item for that purpose.

Mr. WAXMAN. What this bill does, as I understand it, is call for a focus in NIH on this whole subject. What is wrong with that?

Dr. DEBAKEY. I do not think there is anything wrong with it. I am merely saying that you do not need a whole bill for that purpose. It can be achieved in a much simpler fashion by current legislative procedures.

Mr. WAXMAN. Well, in effect, Congress is saying to NIH, we want you to give some attention to this subject. You may feel you have given enough, but we would like you to give even more.

Dr. DEBAKEY. Yes, that is certainly easy to do, and has been done by Congress on many occasions in other areas, where they have said, both in their intent and a line item for appropriations, the statement that they want more money into this form of research or in another form of research.

Mr. WAXMAN. So it is your feeling, if we asked NIH to do this, we should only ask them if we are going to give them more money?

Dr. DEBAKEY. I do not think it can be done without having more money for this purpose. I mean, if you are going to ask them to expand the research for alternative methods, then I think you have to give money for this purpose.

Mr. WAXMAN. Well, how can I believe that? If your earlier statement is correct then scientists are looking for nonanimal uses as part of their regular procedures. Are they not doing this because they are not getting additional money?

Dr. DEBAKEY. No, you are asking a different question. I was responding to a different question. You are asking in a sense to expand the research for alternative methods, nonanimal methods.

Mr. WAXMAN. The specific purpose.

Dr. DEBAKEY. Yes, specific.

Mr. WAXMAN. Just out of some curiosity, is your institution accredited by AAALAC?

Dr. DEBAKEY. No.

Mr. WAXMAN. Why not?

Dr. DEBAKEY. Well, one of the main reasons is that we have asked them to wait until we have this new facility.

Mr. WAXMAN. Then at that time you will ask for accreditation?

Dr. DEBAKEY. Certainly, because we feel with the new facility which we are now planning and actually have the drawings all complete and approved by our board of trustees we hope to start early this year but we have to meet all the guidelines of NIH.

Mr. WAXMAN. Mr. Walgren.

Mr. WALGREN. Thank you, Mr. Chairman.

I am really intrigued, because I think in these statements is this large recognition of the center ground. I am struck by your saying, Dr. DeBakey, that the way to pursue nonanimal alternatives is to appropriate some money for that, in effect. Yet when that suggestion was raised by some members who really felt this was the way to go, and we ought to just decide that and get on with the job, those ideas were criticized as interfering with normal development of the scientific progressions and distorting the competition to do the most effective research at any given point in time.

So, we specifically turned away from allocating more money and tried to go back to the concept of structure, where we can assure ourselves that people are thinking hard about this, and yet we are not interfering with their scientific judgment about where the potential lies and when the proper advances would come along at each point.

I guess what I am asking is, you certainly would not be opposed to the concept of a structure within NIH that at least discusses the contribution that nonanimal research has to make at any particular point in time, and at least calls attention to whatever that contribution may or may not be.

Dr. DEBAKEY. Well, Mr. Walgren, it is not that I would object to anything of that sort. As a matter of fact, that is going on at NIH. As I said, I have been on study sections. I have been on councils. And every major project that comes to our attention has to be approved, and is looked at from that standpoint. Is it necessary to use animals for this particular project? Are there available nonanimal models to do this study?

So, it is being looked at now. Perhaps one of the needs for funds for this purpose is really to try to expand this area by some research utilizing the new technology that has come into being in the last few years, and that is why I said if you want to expand this area, I think you do have to give more funds for research to develop these models.

Mr. WALGREN. Is it your view of the general state of science at this point that nonanimal research could be constructively expanded in terms of the Federal direction of research money?

Dr. DEBAKEY. Mr. Walgren, I would have some difficulty in answering that, because you have to have a crystal ball to answer it. I could only say that I believe there is potential in expanding this area, and this would depend upon, let's say, the research development in this area, because it is established as an area that is in use in scientific study.

The trouble, I think, right now is that the restraints on its use lie in the fact that has not yet achieved that status where it can replace certain animals, and that is what we would like to see, of course.

Mr. WALGREN. If I could ask Dr. Rackow just a general question about the role of alternatives and how you see this bill as either enhancing or creating arbitrary bars to progress of science. We have attempted in the bill, as you know, to avoid any veto powers and any agent in the bill to allow this to happen, but I would like to give you an opportunity to assess the contribution or the difficulty that this bill might raise.

Dr. RACKOW. Well, the bill already states that where animal experimentation is crucial, it should continue. And certainly, as Dr. DeBakey has done in the past, for which the entire world is grateful, is work where animal experimentation was absolutely necessary. There is no alternative for his kind of work, but all medical research is not of that nature, particularly in the field of testing, where alternatives to animal testing seem to be very worthwhile, and seem to have a big potential.

Where animal experimentation is not necessary, and where alternatives can be found, they should be developed. This is where the bill is very valuable. I believe that most of the use of animals is exactly in this field where nonanimal testing has its greatest potential, and therefore this bill would go a long way toward making sure that the total amount of pain and distress in animals is reduced.

Mr. WALGREN. Thank you, Mr. Chairman.

Mr. WAXMAN. Mr. Leland.

Mr. LELAND. Dr. DeBakey, it is a pleasure to see you. Dr. DeBakey happens to be a very good friend of mine, and I am certainly very proud that you would come here today and testify before our committee. Houston is known for several things, the Astrodome,

NASA, and Dr. DeBakey, and we certainly appreciate your being there.

Dr. DeBakey, in the years that you have been both an outstanding surgeon and, of course, a pioneer in the area of heart disease and also a researcher, and particularly associated with Baylor, recognizing that though we talk about alternatives to animal use, that for a long time is going to engage our researchers in animal research, how can you, or can you really tell us, or will you tell us just a little bit of your experience as to how you as a researcher and also your students have engaged in animal research as it refers to the treatment of animals, if you will?

Dr. DEBAKEY. Well, I believe that we are average. I mean, we are representative, I think, of most scientists, at least in my experience traveling around the country and around the world, and in reviewing research laboratories in other places, both officially and as I have on occasions when I was asked by the NIH to do so. In our own institution we have, as I indicated, three committees that review every project, that the concern of scientists is in terms of their scientific work.

And certainly the great majority as far as I am concerned are compassionate individuals who have concern for animals, and are not desirous in any way of suffering on the part of animals.

Second, I think it is important to understand that scientists want to be sure the animals are well treated and are in good health. It takes us approximately $250 to process the animal before he ever goes into the research laboratory, on the average, and that is done largely because we want to be sure that the animal is in good health. It is, of course, supervised by a veterinarian who heads our animal committee for that purpose, the animal care committee.

We try to show our concern in our training program for the undergraduate students but especially for the graduate students because that is where animals are most frequently used in the research center. We try to inculcate this concern for animal welfare in our graduate students, who are going to engage in research.

I believe this is generally representative across the country. Now, I know of instances in which there have been abuses, of course, but at least in our institution if this abuse occurred it would be a major problem for that individual.

Mr. LELAND. Thank you, Dr. DeBakey.

Mr. Chairman, I do not have any further questions relevant to the issue before us. I would like to ask, if I can off the record.

[Whereupon, a discussion was held off the record.]

Mr. WAXMAN. Back on the record.

I would like to make a comment, Dr. DeBakey. I have enormous respect for you and admiration for you, but I really have to tell you I disagree with what you have said here today.

I do not doubt that scientists are people who are concerned about avoiding pain for human beings, certainly, and perhaps animals as well, but it seems to me that human nature is such where you do not think about issues that are not the central issues before you. If the central issue before a researcher is to try to find an answer to a problem, then animals become tools solely in that effort. If we do not suggest that somebody ought to give a priority to looking at other tools aside from animals, I doubt that there will be much priority given to them. I am saying this because I want to hear your response, but I think human nature is such that you do not look at what is not the central task before you.

If we do not say to NIH, we want you to look at this problem, I do not think they are really going to look at it. Now, if you said to me, if you are going to ask NIH to look at a problem you have got to give them money to do it, I appreciate that response. But I have a feeling that if we do not say that this is something we care about, human nature is such that people, good people, kind people are not going to look at it seriously.

I would like to hear you response to that.

Dr. DEBAKEY. Well, of course, Mr. Waxman, that is right. I mean, it is an attitude on the part of human beings to give priorities to certain things, but I think you have got to understand first that the researcher is not working in a vacuum. He is not working alone. He is accountable. He has to respond to the reviews and particularly the peer reviews that the project he initiates goes through, and there are others looking at it, and they are looking both in terms of the cost of it, the merit of it, and whether or not there is any other way of doing this.

The researcher may want to indicate that he wants to use dogs; I can give you specific instances where the committee has indicated that in this particular case we can use mice just as well, and the project had to be changed, even though the researcher originally wanted to use dogs for this purpose. So he is not working alone.

Mr. WAXMAN. So in the review of the project, the peer review, you think those issues are looked at.

Dr. DEBAKEY. I think they have great influence, at least in most institutions. Now, there may be places where they may not have as much influence because they are not structured as well, but I think in the better institutions across this country, they are pretty well structured and they are pretty powerful in that regard.

But let me come back to what you say about this attitude. I am not denying in any way the need to expand this area. I am saying I do not think this bill will do it. I am saying that if you want to really do this, then say to NIH, we want to expand this area, we want you to look at it, we want you to put some money into it, to see what more can be done in this area. This is all I am saying.

Mr. WAXMAN. I thought that is what the bill did.

Dr. DEBAKEY. I do not think the bill does that. I mean, if you look at the bill, it does not specifically say to the NIH that we are going to put a certain amount of money into expanding research in this area.

Mr. WAXMAN. We say to NIH, you put more work on this effort. You know we did that in 1948 when Congress created the Heart Institute. We said to them, we want you to do more work on heart disease, and later came back and put more money into that effort. I think if we had not made that statement to them then, we might not have had some of the advances we have.

Dr. DEBAKEY. I agree with that completely. As a matter of fact, that is one of the reasons I come from time to time before the Appropriations Committee, as you know, to lobby for more money for specific areas of research. Yes, I agree with that completely.

Mr. WAXMAN. Let me get a response—from either Dr. Rowan or Dr. Rackow.

Dr. ROWAN. Thank you, Mr. Chairman.

I would like an opportunity. I have never sat on a peer review committee, so I do not know what goes on in the committee. I am aware that some of them certainly do address the animal welfare issues. But I know of one specific example when Dr. Taub put in a grant application to do work on monkeys and stated that the animals needed extraordinary care. As we all now know, when you differentiate monkeys, they do need extraordinary care, and yet he asked for a per diem cost of only $0.55 a day. This was at a time when the average per diem cost for ordinary care for rhesus and cynomolgus monkeys was $2.50 a day according to NIH estimates.

I find it very difficult to understand how the peer review committee, if they looked at animal welfare issues, could have overlooked such a glaring discrepancy. That is one single isolated example, and I am sorry that it has to come from the case of Dr. Taub, which, has already been overpublicized. But, this example indicates that welfare issues are not necessarily being looked at in peer review committees, at least not all of them.

As another example, there is a technique that is now available for assessing the malignancy of cancer cells using chick embryo skin. Now, this was published in Science a few years ago, and yet it has only been taken up by one institution to my knowledge and yet it seems to be an excellent technique for assessing malignancy, which is normally determined in mice or in guinea pigs.

It is an example of how difficult it is for researchers to keep up with such a wide variety of literature and really keep abreast of everything considering the vast amount of material that is churned out every year.

Mr. WAXMAN. Thank you both.

Anything further, Mr. Walgren. Mr. Leland.

Mr. WALGREN. No, sir.

Mr. LELAND. No, sir.

Mr. WAXMAN. If not, let me thank you for being here today and participating in this hearing.

That concludes our business for today. The subcommittee stands adjourned.

[The following statements and letters were received for the record:]

TESTIMONY OF
BERNARD E. ROLLIN, PhD
DECEMBER 9, 1982

My name is Bernard E. Rollin. I am speaking today both as an individual trained as a philosopher who has been deeply involved for seven years in theoretical and practical issues surrounding the use of animals in our society, and as a representative of Colorado State University, where I hold appointments as Professor of Philosophy in the College of Arts, Humanities and Social Sciences, Professor of Physiology and Biophysics in the College of Veterinary Medicine, and Director of Bioethical Planning. In the last capacity, I work closely and daily with the Laboratory Animal Resources unit, the Animal Care Committee, the Human Research Committee (which I chair), and the Biohazard Committee on specific bioethical issues which arise at any institution engaged in scientific research. Prominent among these issues are many specific concerns pertaining to the use and welfare of laboratory animals.

Colorado State University is a major and vital center of biomedical research. It ranks in the top ten among land grant institutions in biomedical research funding in the United States. Our researchers are at the cutting edge of contemporary science. For example, we are currently involved in animal studies dealing with such problems as cancer, leprosy, tuberculosis, low-level radiation, malaria, hypertension, hip-joint replacement, and embryo transfer. We recently received considerable international attention when our researchers successfully accomplished the cloning of twin calves. Yet, despite this deep commitment to animal research, and indeed because of it, Colorado State University has pioneered in developing a rational and practical approach to synthesizing the requirements of science with our deep moral obligations to the research animals we use. As Dr. Charles O. Neidt, Acting CSU President in 1981 and himself a prominent researcher, said in dedicating our exemplary central laboratory animal facility: "The greater the encroachment on the lives of animals made by humans, the greater the human obligation to be sure that animals are cared for properly."

My own professional activity since 1975 has been devoted to an attempt to actualize that ideal. The intellectual basis for my activity is my book, Animal Rights and Human Morality, which attempts to delineate, in a rational way, what our moral obligations are to animals and how these can be best achieved in our socio-cultural situation without sacrificing the myriad human benefits with which the use of animals provides us. Gratifyingly, the book has been extremely well-received by both scientists and animal welfare advocates, and has garnered excellent reviews in such diverse places as The Journal of the American

Medical Association, The Journal of the American Veterinary Medical Association, The California Veterinarian, The New Scientist, The International Journal for the Study of Animal Problems, and the Times Literary Supplement.

On the basis of the ideas expressed in my book, I have been involved in a number of pioneering projects. I have been primarily responsible for developing the field of veterinary medical ethics into a legitimate object of study, much like human medical ethics. A major aspect of veterinary medical ethics concerns our moral obligations to animals, and this question is now being increasingly addressed by American veterinary medicine. At Colorado State University, I created the first required course in ethics ever to become part of the veterinary curriculum. By the end of this academic year, I shall have lectured on these issues by invitation to more than half of the veterinary schools in North America.

Most directly relevant to the business of this hearing has been my work in laboratory animal legislation. About six years ago, a group of Colorado citizens consisting principally of myself, an attorney, a physician, and two veterinarians and animal researchers, began to meet on a regular basis to discuss the welter of complex issues relevant to this question, with the aim of drafting model legislation. Both of the researchers enjoyed extrordinary experience in the problems associated with the uses of animals in research. One, Dr. Harry Gorman, is a charter diplomate of the American College of Laboratory Animal Medicine, past head of animal research for the Air Force aerospace program, past president of the American Veterinary Medical Association, a prominent

experimental surgeon who pioneered in developing the artificial hip joint, and a man who has over forty years of research experience. The other, Dr. David Neil, is a laboratory animal veterinarian and microbiologist who heads the laboratory animal service at Colorado State University, who designs laboratory animal facilities, and who has enjoyed over twenty years of research experience in Britain, Canada, and the United States.

We all agreed that science will and must continue to use animals in research for human and animal benefit, and that we all supported such good research. We also agreed that the use of animals in research carried with it an awesome moral burden, the obligation to ensure that the animals used were well-treated and well-cared-for, and that any suffering not essential to the purpose of the research be eliminated. In addition, while we realized that the vast majority of researchers would heartily endorse this moral principle, we also knew that moral concern often becomes buried under the pressures of practicality, expediency, competition, the quest for funding, and pedestrian daily activities. For this reason we felt that, like other moral responsibilities which can be easily eclipsed, our obligations to animals needed to be "writ large" in law.

Although legislation pertaining to laboratory animals did exist in the form of the Animal Welfare Act, it specifically disavowed any concern with the actual conduct of research, making it somewhat like a cookbook containing recipes for all parts of a meal but the main course. Furthermore, it arbitrarily excluded from its protection rats and mice, which

constitute 70% of the animals used in research. And while excellent NIH guidelines as specified in the Guide for the Care and Use of Laboratory Animals did exist, they were merely guidelines and were frequently ignored. For example, while the NIH guidelines specifically forebade the use of animals for multiple survival surgery in teaching, that is for surgery teaching where the animals, most commonly dogs, would be operated on, allowed to recover, operated on again, allowed to recover, and so on, sometimes for an entire semester, many schools were regularly violating this prohibition in order to save money.

We further felt that we were living in an age of increasing public demand for accountability in all areas of society, and of an increasing public demand for assurance that laboratory animals were not being abused. At the same time, we realized that one could not police researchers, that it was absurd to imagine "a cop in every lab", and that there was good reason to be heathily skeptical of creating yet another layer of bureaucratic intrusion into such a delicate activity as the research process.

How could all of these factors be balanced in law? The best way, we concluded, was by creating a mechanism which would increase researcher sensitivity to the moral issues surrounding the use of laboratory animals, and which would make conscious concern with these issues a significant vector in the research process. And the best way to accomplish this was to legislatively mandate local responsiblity for these concerns in a process of institutional review, on the analogy of what is currently done for the protection of human subjects in research. The burden of responsibility should be placed on the institution doing the research.

In this way, a process of self-regulation would be created, which must inevitably raise the consciousness of researchers regarding these concerns. Outside members of the committee drawn from the community would demonstrate that the research institution was not attempting to conceal anything, and would in fact actually serve to dispel much of the lurid "science-fiction" which often pervades a community ignorant of what is in fact happening in research, and therefore subject to being influenced by irresponsible rumor-mongering.

Furthermore, we felt that one additional virtue of the plan was that it would involve no significant additional expenses to institutions. All institutions receiving federal funding for biomedical research must already have some form of animal care committee in place. All such institutions would either have laboratory animal veterinarians on staff, or more rarely, on a consultant basis. It would involve relatively little effort to have these committees review projects to ensure that animal pain and suffering were minimized and controlled, for example by proper use of analgesia where such use was not contrary to the design of the experiment. At Colorado State University, the annual cost of running our Animal Care Committee is approximately $24,000.00. At all universities, service on committees is considered part of one's responsibilities as a faculty member, and thus faculty participation involves no expenditure beyond the salary already being paid. Outside members serve voluntarily. The only additional expenses involve employing secretarial staff, providing materials and supplies such as photocopying and coffee, paying overhead, and providing a certain percentage of the salary of some executive officer charged

with administering these committees. The only additional expense which would arise out of the project review at our university is the need for an additional one-twelfth time in secretarial help at an additional cost of $1,550.00. The current cost of running the committee amounts to 0.43% of our biomedical research budget. With project review, this would rise negligibly to 0.45%.

The key points to stress, therefore, are these: First of all, any institution doing any federally funded biomedical research would already have an Animal Care Committee. Secondly, whatever the cost of running the committee at that institution might be, the cost increase required to establish project review as a major function of the committee would be negligible. And thus, this concept, if made into law, will not impose any major fiscal or administrative burden upon any institution engaged in biomedical research.

The results of our thinking in this whole area was incorporated into what became known as the "Schroeder Bill", first introduced in 1980 by Representative Schroeder, which would have amended the Animal Welfare Act to cover the concerns outlined above. The bill under discussion today has preserved the essential features of that concept. And it is for all of the above reasons that I urge its passage, as well as for a number of additional pertinent reasons to be detailed below. I should like to point out now that our institution, Colorado State University, has voluntarily adopted such a review process, and that its adoption was strongly endorsed by most of our researchers. Some of the reasons

given by the scientists for their support are worth detailing here. One scientist said that "we have nothing to hide. No one could be opposed to this unless they had something to hide." Another said that "it will help immeasurably in informing the public as to what we are doing." Dr. David Robertshaw, internationally known physiologist, who serves on the public affairs advisory committee of the American Physiological Society, said that the research community must have an institutionalized conscience which was not dependent on the happenstantial interest of an individual like myself.

Many scientists have pointed out that such review, by virtue of the attention it focusses on controlling the pain and suffering of the animals, can serve to help minimize sources of stress to the animals which might well invalidate the research in question. (It is axiomatic that animals who are stressed in any number of different ways do not yield reliable data, as metabolic variables are skewed in an unpredictable fashion.) Good treatment of animals is not a gift which science bestows on animals or can withhold if it feels like it - it is an absolute precondition for the validity of scientific results, as well as a moral requirement. Far too much money and effort has been wasted on research whose validity was impeached by improper treatment of animals. One notable and unfortunate example is provided by the National Cancer Institute's program of testing possible carcinogens, as reported in Science in June of 1979.

The bill being discussed today also contains an excellent provision which did not figure in our original thinking. I refer to the provision on page 12, line 19 that:

> The (local) committee will establish courses or sessions available annually for scientists, animal technicians, and other personnel involved with animal care, treatment, and use by the research entity, which provide instruction or training in (A) the humane practice of animal maintenance and experimentation, and (B) the concept, availability and use of research or testing methods that minimize the use of animals or limit animal distress.

In the course of talking to laboratory animal veterinarians around the country charged with animal care, I have been told that one major source of animal pain and suffering is that researchers are often ignorant of the needs and natures of the animals they are using in their research. For example, in one case a researcher was losing guinea pigs to what he thought was a disease. In fact, it turned out that the guinea pigs' teeth were maloccluded (not meeting properly), the animals could not eat, and were starving to death! Many researchers do not know how to restrain animals properly, or how to draw blood in ways which do not hurt the animals. The provision quoted above would place an emphasis and priority on educating researchers in these neglected areas, and must inevitably result in better care and better science.

In summary, I can see no cogent arguments against the concept under discussion. It institutionalizes our moral concern for research animals, and does so at minimal expense and with minimal bureaucratic intrusion. It socially underscores our moral obligations to animals, and the accountability of researchers to society. It promotes good science and better public understanding of what science is about. And like all good laws, it serves an educational function, and increases awareness and sensitivity. If this bill is made law, everyone wins - the public, science and the animals. The only losers are those whose work cannot stand the light of day.

INSTITUTIONAL ANIMAL CARE COMMITTEE

CURRENT OPERATION AND EXPENSES

AT COLORADO STATE UNIVERSITY

For An Institution Supporting $5,678,404.00 Biomedical Related Research Directly Associated with Animal Use.

Committee Expenses:

Salary + Benefits Secretary - 1/6 time	$ 3100.00
Materials and Supplies	2000.00
Committee Travel	500.00
Executive Secretary (DVM)	
Time for Project Review (approx 12 da/yr)	2328.00
Time on ACC Tours (approx 6 da/yr)	1164.00
Executive Time (approx 50 da/yr)	9700.00
Correspondence and Notation (approx 14 da/yr)	2716.00
Time Expended by Director of Bioethical Planning (22 da/yr)	2659.32
TOTAL:	$ 24167.32

FUTURE ADDITIONAL OPERATION

Peer Review (ACC) of Funded Projects to be Implemented in 1983 at an Established Cost of:

All expenses from above the same except for ¼ time secretary instead of 1/6 time:

TOTAL: $ 25717.32

Current Cost of Operation for ACC is $24167.32, in support of $5,678,404.00 Animal Research Costs or:

0.43%

Predicted with Peer Review (as in Proposed Legislation). 1983 Costs of Operation for ACC in $25717.32 in support of $5,678,404.00 Animal Research Costs or:

0.45%

Thus, project review would raise the total expenditure for the Animal Care Committee relative to the total research budget by less than three one-hundredths of one percent!

From Dr. Orr Reynolds
Executive Secretary
American Physiological Society

"The American Physiological Society supports the concept of local review as described in the bill and endorses the notion of intellectually credible outside members from the community."

Personal Communication with
Dr. Bernard E. Rollin on
December 6, 1982

Dr. Kirk N. Gelatt, Dean of the College of Veterinary Medicine, University of Florida endorsed the above statement.

Personal Communication with Dr. Bernard E. Rollin, December 8, 1982.

From Dr. Arthur Newell
California Veterinary Medical Association

"There are many honorable foxes, but they are still foxes. So the California Veterinary Medical Association supports meaningful local review with outside members from the community."

Personal Communication with Dr. Bernard E. Rollin, December 8, 1982

Dr. Robert C. Benedict
Assistant Vice President for
Health Affairs
USC

"The Univeristy of Southern California regards an animal ethics review board with a member from the community as an indispensable mechanism for assuring balanced judgement of biomedical research needs and assuring highest ethical standards in humane care and treatment of live vertebrate animals used in the research process."

Personal Communication with Dr. Bernard E. Rollin, December 8, 1982.

aamc association of american medical colleges

Statement of the

Association of American Medical Colleges

on H.R. 6928

"The Humane Care and Development of Substitutes

for Animals in Research Act"

The Association of American Medical Colleges (AAMC) appreciates this opportunity to share its thoughts on the very important and complex issues raised by H.R. 6928, "The Humane Care and Development of Substitutes for Animals in Research Act".

The members of the AAMC are involved not only in the undergraduate and graduate education of physicians in medical schools and teaching hospitals, but also in biomedical and behavioral research. The constituency of the Association includes all of the 127 medical schools in the United States, over 400 teaching hospitals and 70 academic and professional societies whose members are engaged in the delivery of health care, medical education, biomedical and behavioral research. As such, this organization represents the largest single component of the Nation's biomedical and behavioral research enterprise. Thus, the subject of this hearing is of deep concern to our membership.

Submitted by the Association of American Medical Colleges to the Subcommittee on Health and the Environment of the House Energy and Commerce Committee. December 8, 1982.

BASIC PREMISES

Prior to outlining the Association's response to the specific bill in question, a brief discussion of the premises on which these views are founded would appear useful:

- First and foremost, the Association is of the firm belief that the overriding goal of scientific investigation is the protection and enhancement of human life. In the constantly evolving frontier we know as biomedical and behavioral science, achievement of this goal is heavily dependent upon the development of new drugs and a host of therapeutic modalities which almost always require research in living organisms, and, eventually, in human subjects. By definition, all such experimentation entails some degree of risk---risks which must be taken if the human condition is to advance and our society is to be rid of the suffering and disease which diminish the quality and duration of life for millions of Americans.

- A vital and necessary component of this endeavor is the utilization of animals for experimental purposes. In many cases, *in vitro* methods complement research in living organisms and may well result in a reduced reliance upon animals at some point in the investigative process. However, the basic reality is, that for many forms of bioassay, adequate alternatives simply do not exist because of the impossibility of replicating

in vitro all of the systems---many not yet completely understood---of a complex higher organism. Moreover, the important and delicate interrelationships of these systems are not yet understood nor is their functional behavior predictable with any degree of accuracy.

- The Association is unalterably opposed on ethical grounds to the mistreatment or unnecessary use of animals in research. Humane treatment of these creatures is essential to high quality scientific investigation. Accurate and valid data cannot be derived from experimentation upon sick, poorly maintained or abused animals; and finally
- The AAMC is fully supportive of reasonable proposals to develop methods which reduce or eliminate the use of animals whenever possible.

It is from this perspective that the AAMC addresses this proposal.

"THE HUMANE CARE AND DEVELOPMENT OF SUBSTITUTES FOR ANIMALS IN RESEARCH ACT"

Overall Concerns

In terms of the specific legislation in question and the report issued by the Committee on Science and Technology, the Association has several overall concerns:

- While H.R. 6928, as reported, represents an improvement over previous versions, it remains vague in intent and unnecessarily costly; it could also

prove detrimental to scientific progress and intrusive upon the decision making mechanisms of virtually all research institutions, while offering little in the way of redeeming benefits.

- The enactment of the extremely detailed standards prescribed in the bill is ironic: it would enshrine a much higher degree of statutory protection for animals in research than currently exists for human subjects.
- The compliance costs that would have to be borne by a steadily diminishing research enterprise must be carefully weighed against the putative benefits that adoption of this bill would yield to the well-being of our society. The price of implementing H.R. 6928 recognized by the Congressional Budget Office, is extremely high:

> "Researchers at NIH estimate that the cost to research entities for accreditation would be $500 million in total or about $50 million over the ten year life of this bill. Also, about 1,300 additional staff would be necessary to meet the reporting requirements of this bill. Using an average cost of $50,000 per employee, the cost to research entities for additional manpower would be $65 million per year. NIH would require 5 additional staff at a cost of $250,000 per year."

It is worth noting that on an annual basis---based upon Fiscal Year 1981 prices---this is equivalent to the cost of approximately 1,270 traditional (R01) NIH grants.

The justification for requiring such an enormous expenditure of funds is far from clear and is glaringly absent from the Committee's report on the bill. The assumption that it is needed to insure the humane treatment of animals is highly questionable. The reality is that humane treatment of animals is already standard procedure, since it is essential to high quality investigation---accurate and valid data cannot be derived from experimentation upon unhealthy, undernourished, poorly maintained or abused animals.

Outlined below are the Association's comments on the specific provisions of the bill.

Title I: Development of Improved Research and Testing Methods

Non-Animal Testing Methods. The bill would authorize the Secretary of the Department of Health and Human Services (HHS) to make awards to sponsor the development of research, experimentation and testing which:

- Do not require the use of live animals.
- Reduce the number of animals used or produce less pain and distress than methods currently in use.
- Establish the validity and reliability of such methods for replacing present animal research and training and testing methods.

Overall, the AAMC is convinced that the premises on which these provisions are based are false. Most significant advances in research methodology occur in the course of scientific investigation having an identified substantive, rather than methodological, objective. Whatever the specific research goal, a constant search for improved and more precise methodology occurs predictably. Existing methods that complement those using living animals have usually been the consequence of the pursuit of a different objective---such as the development of a new therapeutic agent. Therefore, in these times of limited funding one can only question the wisdom of separating these two objectives.

In the final analysis major medical advances have been and will most likely continue to be contingent upon the knowledge and data garnered from animal experimentation. As noted previously, alternative methods, in most important instances, can only complement animal research. It is noteworthy that 44 of the Nobel Laureates in Physiology and Medicine, since the program's inception in 1901, accomplished their prize-winning research through the use of animals. Animal based research is also responsible for two recent astounding earmarks of progress in human health ---the artificial heart and the infant liver transplant.

Despite the progress made to date in *in vitro* methods, there are many, many areas in which animal research remains crucial to the protection or improvement of human life because the potential of alternatives to testing in the complex of physiological and psychological systems found in the intact animal are quite limited. While these areas are too numerous to record here, an enumeration of a few would prove illustrative:

- Atherosclerosis, the leading cause of death in the U.S.; cell cultures and biochemical and immunologic analyses may yield valuable data at the cellular and molecular levels on causation and potential therapy but definitive validity must still be established in intact animals.
- Cardiac valvular surgergy for patients with congenital and rheumatic heart disease; bypass graft surgery in patients with coronary artery disease
- Cardiac pace makers for patients with disabling arrythmias
- Therapy to decrease the size and severity of myocardial infarction
- Neurologic diseases and impairments including strokes, multiple sclerosis, amyotrophic lateral sclerosis, epilepsy, myasthenia gravis, brain and spinal cord tumors
- Spinal cord regeneration
- Hypertension and the recognition of the role of the kidney in both cause and effect that led to the development of its treatment with diuretics
- Transplant surgery, initially of kidneys and now of other organs, including: pancreatic transplants for diabetes mellitus; liver, lung, heart transplants
- Mental illness
- Prosthetic devices, such as artificial hip joints, to compensate for a host of physical limitations.

- Diabetes, a disease which afflicts 4% of the population of the United States.
- Eye disease and ailments, including cataracts and glaucoma
- Hyaline Membrane disease---the problem that accounted for the death of President Kennedy's infant son--- whose mortality is now less than 10% compared to 90% fifteen to twenty years ago.
- Meningitis
- Aplastic anemia, lupus, leukemia and other forms of cancer
- Development of new vaccines and antibiotics to fight the many infectious diseases still in existence, such as infectious hepatitis B and leprosy
- Advancement in the understanding of emphysema and other respiratory diseases.

In addition, several other concerns are generated by this concept of "alternative methods":

- There are powerful economic incentives to substitute non-animal methods wherever possible. Research involving animals is extremely costly: it entails their purchasing, care and feeding, the expense of maintaining the necessary staff to fulfill these functions, as well as the additional responsibility of insuring proper adherence to a host of animal care regulations, guidelines, and reporting requirements.

In these times of ever less adequate support, reducing costs of scientific research by using non-animal methods is highly attractive to investigators. Progress in this direction is attested to by the results of a study conducted by the Institute for Laboratory Animal Resources of the National Academy of Sciences National Research Council demonstrating an almost 40% reduction in the number of animals used in research in the period from 1968-1978.

- As a general purpose mechanism to achieve the desired end, these provisions would be inefficient, ineffective and unproductive. Development of new techniques would seem at least possible---and would certainly be desirable---in a limited domain---namely testing; however, this arena of opportunity should be identified more precisely in the proposal. Moreover, given recent and substantial private sector commitments to R&D in this area, the need for Federal support of any degree or type should be more closely evaluated and convincingly justified.

Title II: Federal Award Requirements

Accreditation Requirements. Section 202 mandates that, within ten years of enactment of this legislation, a research entity must obtain certification that it is qualified to engage in research

involving animals by a recognized accrediting agency. It is the Committee's intent that the American Association for Accreditation of Laboratory Animal Care (AAALAC) be designated as the accrediting agency.

It must be recognized that, while most facilities meet adequate and desirable standards, AAALAC's requirements exceed what is essential to ensure the humane care and treatment of laboratory animals. Thus, the financial stress that compliance with this mandate entails is not justifiable. The accreditation expenses, as embodied in the CBO's comments on the bill, are hardly the normal costs that would be incurred "within a time frame comparable to normal facility modernization and/or replacement cycles" as implied by the Committee Report. The Association believes the standards prescribed under the Animal Welfare Act of 1966 are sufficient to insure the humane care of research animals and would suggest that the Animal Plant and Health and Inspection Service (APHIS) continue to be responsible for the implementation of the provisions of the Act---although additional funding for APHIS to fulfill these functions would certainly be necessary.

In addition, this section raises additional issues:

- The bill requires that the accrediting body possess the ability "to ascertain the qualifications, background and experience of research entities in the use of animals..." AAALAC, currently addresses only the care of animals and facility specifications. The provision mandates the review and approval of characteristics associated with and related to specific research

protocols, not of the central animal care facilities and personnel. Judgement in the domain of use should be made by qualified reviewers as new projects are proposed, rather than by accreditation teams at a single moment during a periodic, usually quinquenial site visit.

- Should AAALAC not be designated by the Secretary, the phrase, "private agency or agencies" raises the potential for the creation of a large number of different private agencies, each using its own standards, to oversee animal care programs related to Federal research expenditures. In the Association's view, the responsibility to regulate the conditions under which Federal funds are used should remain Federal.
- The bill would establish statutorily an inappropriate relationship between the federally designated accrediting body and a component---the animal studies committee---of the entity seeking accreditation. Communication from the accrediting body to the research entity should be at "arms length" except to the extent necessary to assure that the entity possess sufficient information concerning its obligations to meet the prescribed accreditation standards.

Assurance Requirements. Section 203 would essentially cast in statute many of the details and policies set forth in the NIH's "Policy on Humane Care and Use of Animals," including the establishment of Institutional Animal Studies Committees. Incidentally, these guidelines are currently undergoing revision: they will be published for public comment this spring and a series of hearings to elicit public comment on them will be held around the country.

Of concern to the Association are several of the provisions which would extend, unreasonably, beyond the NIH Guidelines. Specifically, the bill would require that:

- Animal studies committees make scientific determinations concerning both modifications of experimental designs and the use of animals for research purposes. The composition of the Committee does not suggest or require that the individual members possess the expertise necessary to make sophisticated evaluations of a wide range of experimental designs nor to assess the necessity of using animals; these judgements have always been made through the national system of peer review. This fundamental fact does not support the disclaimer in the Committee's Report that requirements won't "supplant or interfere with the normal peer review process". Moreover, already published in the NIH's "Handbook for Members of Scientific Review Groups" are instructions to the study sections to determine the necessity of using vertebrates in each protocol submitted. Finally, such additional responsibilities would markedly increase the committee's workload.

- Committee members be "encouraged individually to notify the Animal and Plant Health Inspection Service of the Department of Agriculture, the responsible Federal agency and the accrediting agency of any unacceptable conditions of animal care, treatment or use which have not been reported in writing by the committee as a whole or which have been persistently neglected despite notificiation to the research entity". Such a requirement could prove highly divisive and disruptive in terms of the management and activities of committees and its intrinsic presumption that misconduct is likely to occur and could well be so distasteful to honorable participants as to discourage them from assuming the burdens such committee work entails. It should also be noted that no similar requirement is embodied in the regulations governing the conduct of research involving human subjects.

Title III: Federal Agency Review of Award Proposals

Section 301 would prohibit Federal agencies from funding any research, experimentation or testing proposals involving animals unless certain requirements were met. Overall, the Association believes that these would, in many instances, be extremely difficult to operationalize:

- In any case involving the "direct use of conscious animals", assurances would be required that a consulting veterinarian had been employed in planning these

procedures. The feasibility of this requirement must be questioned, as it is dubious that the national pool of qualified veterinarians is large enough to satisfy such a requirement. Moreover, the actual benefits to be derived from such a requirement are dubious.

- A justification for "anticipated animal distress in terms of the benefits of the research" would be mandated. This would be virtually impossible to operationalize as such a specification does not exist even for research involving humans, where an approximately quantitative measure of the phenomenon of suffering is at least possible.

- Assurances that no animal shall be used in more than one major operative procedure from which it is allowed to recover, except in cases of scientific necessity or other special circumstances as determined by the animal studies committee. Again, as stated previously, these committees do not possess the necessary expertise to address these issues.

The Association and its constituency would be happy to further discuss the problems and issues raised by this legislation with the members of this distinguished Subcommittee and their staffs.

SCIENTISTS GROUP FOR REFORM OF ANIMAL EXPERIMENTATION
147-01 THIRD AVENUE
WHITESTONE, NEW YORK 11357
(212) 767-8670

STATEMENT IN FAVOR OF ENACTMENT OF H.R. 6928

by HERBERT RACKOW, M.D.

BEFORE THE SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

OF THE COMMITTEE ON ENERGY AND COMMERCE

December 9, 1982

Mr. Chairman and Members of the Committee:

I am Dr. Herbert Rackow. I am a member of the Board of Directors of the Scientists Group for Reform of Animal Experimentation, and I am presenting evidence on their behalf.

I received my M.D. from Howard University College of Medicine and then joined the full-time academic staff of Columbia University College of Physicians and Surgeons. I remained at Columbia University for 25 years until my retirement as Professor Emeritus Anesthesiology. I specialized in pediatric anesthesia and was the first Chairman of the Anesthesia Section of the American Academy of Pediatrics. During the time I was at Columbia, I did both clinical practice and clinical and animal experimental research in absorption and excretion of anesthetics, and most of my publications are on this subject.

I want to say that animals are important tools for research

in medicine and the biological sciences. Therefore, as a physician and scientist, I am concerned about future restrictions on the use of animals in these fields; however, I am also concerned about the ethical considerations in this use of animals because an animal is much more than a tool. This dilemma is well expressed in the findings of this bill, H.R. 6928, Section 2, that the public is interested, that animals used in scientific research and testing be treated humanely, that alternatives be developed where possible, that whenever an experiment is crucial, it should continue, but that pain and distress be minimal, and that institutional arrangements are needed to reflect these concerns.

My own research career was very much affected by each of these considerations. As a young scientist, I was advised by the senior members of my Department to do my research on animals, but I had two important reservations regarding this advice. I was really interested in studying anesthesia in man, not in animals, and I did not approve of using animals unless it was absolutely necessary.

To this end, I planned my research so that I could use as subjects hospital patients who had to be anesthetized for surgery. This did delay the start of my work inasmuch as I had to make absolutely sure that no risk to patients was introduced because

of the research. To ensure this, each member of the research team acted as a subject in the preliminary testing of the research equipment before it was used on hospital patients. In the end, the total risk to the patient was actually less while we studied the course of anesthesia because of the additional monitoring and other safeguards we used which would not have been used during standard clinical anesthesia. The research work eventually did lead to a better understanding of how to avoid overdose of anesthetics in man.

I think if this bill had been law 30 years ago, I would not have been encouraged by the senior scientists in my Department to study animals, but to study man directly, as I did. This bill should help to correct a mistake all too common among scientists of automatically using animals to study problems without giving much thought to other and possibly better alternative methods.

Statement of the Association for Biomedical Research

The Association for Biomedical Research respectfully submits the following comments for the record regarding H.R. 6928, "the Humane Care and Development of Substitutes for Animals in Research Act."

The Association for Biomedical Research represents nearly 200 universities, medical schools, veterinary schools, research institutes, animal suppliers, and pharmaceutical, chemical, and contract testing companies. ABR's primary objective is to assure the humane and responsible use of laboratory animals in biomedical research and testing. ABR is the only scientific trade association which represents both industry and academia on this important issue.

While H.R. 6928 addresses issues of concern as expressed by both animal welfare and scientific organizations such as ABR, we believe several components of this legislation place costly and time-consuming administrative and financial burdens on research facilities, which could adversely affect the orderly conduct of biomedical research.

Specifically, the ABR membership is concerned with the following provisions of H.R. 6928.

Title II -

Section 202 - Accreditation - the National Institutes of Health have estimated that the costs to existing research facilities to meet the accreditation requirements as proposed in this section would be $500 million. Even though research facilities are given 10 years to meet these requirements, many responsible research projects would be placed in jeopardy if major financial resources to meet these requirements are not identified. While AAALAC is an excellent organization, its high standards may not be met by research institutions with currently limited financial resources. However, the Subcommittee must understand that lack of this standard of accreditaton does not preclude the conduct of high quality research.

ABR recommends that, prior to any enactment of this legislation, a definitive study be conducted to determine the exact cost to U.S. research facilities to reach AAALAC accreditation standards. At that time, enactment of this legislation should address possible ways of financially assisting those research facilities which otherwise, have no hope of attaining the necessary financial resources.

Section 203 - Assurances Required from Research Entities - As the Subcommittee is aware, all research institutions which compete for NIH funds must file assurances stating that their institutions have animal care committees. The animal studies committee as outlined in H.R. 6928 has duplicative and seemingly extensive bureaucratic responsibilities which fail to insure that these committees would be any more effective than the existing required institutional animal care committees. Rather, the many responsibilities placed on these committees in the proposed legislation require an inordinate number of man-hours and may, in fact, detract from their effectiveness. Further, the costs of administering these committees as presently outlined are prohibitive. It has been estimated that it will cost U.S. research facilities $65 million just to administer the committees.

ABR also suggests that the study recommended above also determine the actual costs to research facilities of administering the proposed animal studies committee.

In regard to the addition of a member of the community on the animal studies committee, it is imperative that the Subcommittee add a provision in the legislation concerning confidentiality. Serious problems can arise in relation to disclosure of confidential and proprietary information unless a specific confidentiality statement is included in the legislation and the subsequent regulations.

While H.R. 6928 appears responsive to both scientific and animal welfare concerns, enactment of such legislation is in our view, ill-advised, until the true costs of H.R. 6928 to research facilities have been determined. Additionally, ABR would like to take this opportunity to point out to the Subcommittee that at the present time, there is no accurate analysis of the status of animal research in the United States. Prior to or concurrent with enactment of any legislation regarding animal use, Congress should have information pertaining to the type and number of biomedical research projects underway, and the number and types of animals related to them; a status report of the physical condition of existing research facilities; the types of research in which animals are deemed unnecessary; and advancements currently underway in non-animal research

ABR would like to take this opportunity to offer the expertise of our membership to assist the Subcommittee in further deliberations regarding this issue which is so important to future scientific excellence.

SOCIETY FOR ANIMAL PROTECTIVE LEGISLATION
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Washington, D.C. 20007

(202) 337-2334

STATEMENT IN SUPPORT OF H.R. 6928

BEFORE THE SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

by Christine Stevens, Secretary

December 9, 1982

The Society for Animal Protective Legislation urges prompt enactment of H.R. 6928 with one amendment. The bill has been given thorough and careful scrutiny by experts from both the animal welfare and scientific community. Major representatives have publicly gone over the phraseology, subsection by subsection, something which had never previously occurred. The result: "an unexpected level of acceptability"* to those who attended the series of five meetings, with some hold-outs by those who stayed away from them and so continue their previous adversary positions.

The distinguished Subcommittee should act to end the confrontation by reporting H.R. 6928 favorably so it can now go to the floor for a vote. Because of two sets of hearings held in the Subcommittee on Science, Research and Technology under the Chairmanship of Doug Walgren and the thorough discussions in the full Committee on Science and Technology before reporting out the final bill, there has been an extensive opportunity over a period of more than a year to comment and obtain meritorious changes. The time has come for action for the benefit of tens of millions of laboratory animals and for the benefit of the nation's medical schools and other institutions receiving funds from the

*Letter from Dr. O. Reynolds, Executive Vice President, American Physiological Society, to Congressman Don Fuqua, Chairman, Committee on Science and Technology, August 2, 1982

federal government for research or testing using animals.

The provisions of the bill cannot possibly impede research; instead they will, in many cases, improve the likelihood of scientific accuracy through improved treatment of animals or the use of nonanimal methods whose development is encouraged by Title I.

I will first discuss the need for the chief provisions of Titles II and III which address direct effects on those animals in laboratories at any given time. Most important of these are Sections 203 and 301.

Section 203 predicates eligibility to receive a federal award on the establishment of the research entity of an animal studies committee not unlike the committees already required by the National Institutes of Health of its grantees, with the important exception in 203 (b), "at least one member is not affiliated with the research entity or parent organization and is primarily responsible for representing community concerns regarding the welfare of the animal subjects."

The institution selects this person, who must be a volunteer since payment by the institution would disqualify the individual by making him or her affiliated.

The beneficial effects to be derived from this provision are numerous, not least being that an interested person is brought in to assist with inspection of animal facilities without cost to the government or to the institution. Thus development of bad conditions can be headed off rather than becoming chronic as they, unfortunately, tend to do once begun. The animals are the primary beneficiaries, but the research or testing is simultaneously protected from being thrown off by unassessed variables--the bane of scientific inquiry.

The unpaid member of the committee from outside the institution should bring a useful perspective to consideration of the welfare of each animal subject. The independence of this individual is the key to prevention of inhumane habits

of thought which tend to be self-perpetuating in a static situation.

In the course of my duties as president of the Animal Welfare Institute and secretary of the Society for Animal Protective Legislation, I have visited many laboratory animal facilities. Indeed we have prepared books, Comfortable Quarters for Laboratory Animals, Basic Care of Experimental Animals, and Physical and Mental Suffering of Experimental Animals, which we provide free on request to scientific institutions in an effort to give useful information to people in laboratories who want to reduce animal suffering and to break through the apathy of the many who are indifferent to it. A committee member charged with thinking about the animals' feelings could be a living presence to put forward on a continuing basis the best available information in the field, including advances in development of substitutes for laboratory animals.

The bill calls for annual courses or sessions for scientists and personnel involved with the animals on humane treatment of animals and the "concept, availability and use" of methods that "minimize the use of animals or limit animal distress." My father, Dr. Robert Gesell, as Chairman of the Department of Physiology at the University of Michigan Medical School, gave an annual lecture to the graduating class of students of physiology on their responsibilities and obligations to experimental animals. Though I do not know whose is the concept the courses or sessions called for in H.R. 6928, I know it is workable and useful.

The provisions surrounding the animal studies committee make clear the simple working procedure: meetings to consider methodology of projects as this affects the animal subjects well being or pain; semi-annual inspections of the animals; provision for minority reports should consensus not prevail and for reports by individual members to the granting agency on any persistent noncompliance;

protection of employees who report violations. These comprise the practical framework for encouraging considerate treatment of animal subjects without necessitating large outlays by the federal government for such projects as increased NIH site visits by high salaried individuals. Site visits have their place, but they have been notoriously unsuccessful in improving the welfare of experimental animals. I attended a meeting at NIH a few years ago at which a site visit was described which included a mouse room so filled with ammonia vapor resulting from a combination of dirty cages and poor ventilation, that everyone's eyes were watering as they walked through. But to the distress of institutional personnel who hoped the distinguished visitors from afar would demand a clean-up, the animal room visit passed without comment, and the grant continued without so much as a suggestion that sanitation or ventilation be improved.

Equally, or perhaps more, startling were the facts elicited in sworn testimony at the trial of Dr. Edward Taub for violation of the Maryland anti-cruelty statutes. The NIH site visitor, asked whether she had inspected the animal rooms in question, replied with a shocked, "Oh no!" which told volumes about the prevalent NIH attitude on priorities in site visits.

Some of the photographs of monkeys at the Institute for Behavioral Research and their surroundings, including such items as the refrigerator in which medication and food were kept,are in the packets prepared for subcommittee members. You will note the medication going back to 1969, the rotting apples in the refrigerator, the rotting bandages on some of the animals' arms, the monkey chow fallen into the fecal tray for lack of any utensil to hold it, the hungry monkeys reaching to retrieve this filthy food. The testimony showed that the pellets were

thrown into the cages and those animals which experiments had handicapped had great difficulty in catching them before they fell through the wire mesh cage bottoms. Quite often the ill paid students who came in at irregular hours to provide what little food, water and cleaning there was, simply failed to show up at all. All day and all night the lights burned brightly for lack of repair of an electric switch. Yet Dr. Taub asserted that the care his monkeys got was standard for primate facilities throughout the United States.

It is a sad fact that, despite the fact that NIH had been alerted of bad conditions at IBR as early as 1979, the grants continued with no questions asked until the local police abundantly demonstrated the need for NIH to review its actions in providing some two million dollars of tax-payers' money to IBR. At last the grant was suspended and later cancelled. This would never have happened without outside intervention.

It should not be necessary to go to police and press to obtain decent treatment of experimental animals. Enactment of H.R. 6928 can head off occurences such as this which are tragic for the animals involved and detrimental to the future of responsible scientists.

The costs to each institution of establishing an animal studies committee as provided in H.R. 6928 are insignificant. Opponents of the bill have put forward inflated estimates as a means of killing the bill. The fact is, this is by far the least expensive mechanism that can be adopted in a country of this size with so large a number of entities that use animals for experiments or tests. A somewhat similar system for reviewing experiments on human beings has proved workable and served as a model for similar provisions in H.R. 6928.

Cost of accreditation as proposed under the bill has also been criticized as too costly, and we believe this distinguished subcommittee would do well to put off final decisions on this subject by adopting the amendment which Senator Dole added to his companion bill S. 2948 as follows:

"Sec. 202 (a) in order to be eligible to receive a Federal award for the conduct of research, experimentation, or testing, involving the use of large numbers of animals, a research entity shall provide to the responsible Federal agency evidence that it has met requirements to engage in such use as required by the Secretary under this title. The Secretary shall, by regulation, prescribe the form and manner in which such evidence shall be presented.

(b) (1) Prior to the issuance of regulations and within one year of the date of enactment of this Act, the Secretary shall conduct a study to determine the possible economic impact of accreditation on biomedical and behavioral research facilities using live animals. The purpose of the study shall be to determine the costs of meeting standards comparable to those specified in the National Institute of Health "Guide for the Care and Use of Laboratory Animals."

(2) After completion of the study provided for in paragraph (1) the Secretary shall issue regulations for implementing specific standards based on the results of the study. Such regulations shall also provide for waiver by the Secretary of accreditation requirements that cause an undue economic hardship on research entity."

Institutions conducting biomedical research are not always so cost-conscious as they appear to be when criticizing this bill. For example, the foundations that donated funds to build the Stanford Outdoor Primate Facility pictured and described on pages 20-27 of "Comfortable Quarters for Laboratory Animals" protested in vain, even threatened to sue Stanford University, but the University sold the chimpanzee occupants of this remarkable complex and sent them to institutions where they are confined to cages. The expensive, carefully designed great ape facility was simply rejected and no longer benefits any of this class of animals.

On the other hand, reports by the U.S. Department of Agriculture's Veterinary inspectors under the Federal Animal Welfare Act show persistent deficiencies in many of the different departments using experimental animals at Stanford. This information is on record with the subcommittee.

When excellent animal quarters built with funds donated for the purpose and used in humane research are rejected while bad conditions for animals persist in many of the other parts of a major, heavily funded institution, it is clear that H.R. 6928 is needed to rectify such situations.

It has been suggested by opponents of the bill that other laws or regulations already cover the matters addressed by HR 6928. The Food and Drug Administration's Good Laboratory Practice regulations have been cited in this connection. Such a citation indicates confusion between legislation designed to prevent needless suffering of laboratory animals and to use animals only when necessary, and regulations drawn for the purpose of stopping so-called "graphite research" and other fraudulent practices which together with incompetence and low animal care standards were giving erroneous information on drugs and other products.

HR 6928 has struck a remarkably intelligent balance in an area far more controversial in the past than it is today. It owes much to the input of scientists and administrators who took the time to examine both content and phraseology in meetings with animal welfare organizations. Thus the valuable provisions for minimizing pain and distress are readily comprehensible to both scientists and laymen. These provisions apply wherever pain or discomfort is more than minor or momentary. Appropriate pre- and postsurgical medical and nursing care, including proper use of anesthetics, analgesics and tranquilizers are required, and neither pain relieving drugs nor euthanasia may be withheld merely because they are thought to be too much trouble.

Paralytics are listed among drugs that must be used properly and report language from the Science and Technology Committee makes clear that their control is what is meant. Such substances, which can result in a nightmare of pain and fear because animals are unable to move or cry out, should never be used casually or routinely. They are employed in both human and animal surgery in conjunction with full anesthesia, but experiments in which the anesthesia is allowed to wear off present grave danger of severe suffering to cats and primates held in stereotaxic instruments.

The subsection taken from the NIH Guide which relates to prevention of repeated use of the same animal for major operative procedures is important and will save needless suffering.

The definition of "direct use of conscious animals" makes clear the distinction between experiments in which an animal is anesthetized and passes directly into death and experiments in which the animal is brought back to consciousness of pain.

The animal studies committee is charged with responsibility of ensuring that when methodology is changed in a project that it does not do so in a manner adversely affecting animal welfare. The investigator is the sole person responsible for the design of his experiments and there is no interference with existing peer review procedures in the bill. But the welfare of the animals remains as a constant -- a great plus for the institution itself and valuable to it from the point of view of its public image.

Stress caused to some animals for want of opportunity to exercise is also briefly addressed in the bill by including exercise among standards for accreditation.

Development of nonanimal methods is established as the intent of Congress by Title I of the bill. Because of the tightness of the federal budget no

authorization for additional funding is made. However the National Toxicology Program has over $62 million for FY83 and is directed to significantly increase its resources for research into development of better tests. This should result in valuable progress in the area.

The Secretary is directed to promote development of new nonanimal methods by associated agencies and to promote them, too, through international cooperation, another nearly untouched field for reduction of the totals of animals used.

This country is estimated to use more animals for testing and research than any other nation in the world--possibly as many as all the rest put together. It is our plain duty to ensure that unnecessary use be curbed. But we have a serious problem in that animal breeders, dealers, and importers are constantly seeking the exact opposite. They want to increase the purchase of animals to the largest possible degree. I would quote from the October-November issue of the Animal Welfare Institute Information Report:

> "The upsurge in use of animals for testing is reflected in a presentation to the New York Society of Security Analysts April 6, 1979, by Dr. Henry L. Foster, President of Charles River Breeding Laboratories, Inc. The figures show an increase in sales from $3.9 million in 1968 to $24.4 million in 1978. As reported in The Wall Street Transcript of May 21st, Dr. Foster noted:
> '...if you read the papers, everything seems to have carcinogenic effects. But that means more animal testing, which means growth for Charles River...TOSCA (Toxic Substances Control Act) and the GLP's (Good Laboratory Practice regulations) should mean the use of more animals, and we believe, the use of more Charles River animals...
> 'Just let me take a few more minutes and read you a list that rather excites us. It is a partial list of people who are building substantial facilities for laboratory animals.
> 'Herkes Chemical (Herkes Pharmaceutical) Hanover, New Jersey 50% expansion in progress, will be completed in 1979. We have 95% of their animal business at this juncture. No guarantee that we'll have it in the future but that's the way we stand now.
> (a list of names of companies that are building animal testing facilities follows)
> '...this is just a partial list of the major ones we thought would be familiar to you. So you can see why we continue to be enthused and excited...'"

Approval of HR 6928 by the Subcommittee on Health and the Environment would take a moderate but very effective step towards ensuring that animals not be used as if they were mere laboratory equipment, in any numbers and in any way. The public wants to know what is occurring inside laboratories. They want to limit animal suffering. We strongly urge prompt action to report HR 6928 from the subcommittee.

TESTIMONY OF

THE AMERICAN PSYCHOLOGICAL ASSOCIATION

and

THE ASSOCIATION FOR THE ADVANCEMENT OF PSYCHOLOGY

December 20, 1982

The American Psychological Association (APA) and the Association for the Advancement of Psychology (AAP) appreciate this opportunity to submit a statement concerning H.R. 6928, the Humane Care and Development of Substitutes for Animals in Research Act. We are in complete agreement with the humane objectives of this legislation. However, we are concerned whether provisions within H.R. 6928 -- though well-intended -- would actually accomplish the goal of improving care.

The Committee is aware that the use of live animals in laboratory research has been a controversial issue in recent sessions of Congress. APA and AAP have expressed several concerns as participants in this debate. Also submitted is testimony we presented in earlier hearings in which many of these concerns are raised. We would like to raise only four here, with special emphasis on some of the many unanswered questions that surround this legislation.

They are:

1. Costs of implementing H.R. 6928;

2. Adverse effects of H.R. 6928 on behavioral research;

3. Composition of the animal studies committee; and

4.. Ambiguous terms and exclusions.

Costs of Implementing H.R. 6928

We believe some of the provisions of H.R. 6928 would have an adverse impact on research institutions stemming directly from the costs involved in the accreditation provisions of Title II, and indirectly from the possible redistribution of resources that would result from the requirements of Title I to develop research alternatives to live animals.

There are currently 422 animal laboratories in our country, out of an estimated 1,200-1,600 total, that are accredited by the American Association for Accreditation of Laboratory Animal Care, the only accrediting body eligible under the provisions of Title II. This means that the majority of our nation's animal research laboratories -- including many federal laboratories -- do not meet standards such as those for wall thickness and the number of windows that would be required if this bill were made law. It has been estimated by NIH that upgrading these laboratories would cost $500 million over the next 10 years. Another $650 million would be required for additional personnel and administrative costs in these labs.

Expense is a particularly critical issue since these costs would be incurred at a time when institutions are experiencing dramatic reductions in federal support. These accreditation standards could have a Catch-22 effect

of cutting off federal research support if universities are unable to meet standards due to reductions in federal support already being experienced.

Some have speculated that the 10-year compliance period set forth in H.R. 6928 would allow most of the expense to be spread out and incorporated in the normal course of upgrading research facilities. This is a critical assumption. If it is not realistic, enormous research efforts would be jeopardized since federal support would have to be diverted to rebuilding facilities. Clearly, there is a need to develop the most current and detailed estimates possible. Accurate cost estimates are essential in determining the direct impact of this legislation on research.

Adverse Effects of H.R. 6928 on Behavioral Research

Psychology involves the study of behavior. This means studying live, health, intact animals. A particular concern for behavioral scientists is that there are few, if any, alternatives to live animals in the study of behavior. Yet, Title II of the legislation calls for alternatives to be developed. While this Title calls for adherence to the standard peer review procedures and is sensitive to the requirements of confirming research methods, resources would necessarily be diverted from research using live animals. This would occur, if for no other reason because no "new" money is provided for research on alternatives. Behavioral science would be one of the most adversely affected fields, since it is less likely to benefit from the search for alternatives. This raises questions about the opportunity costs

involved in favoring one area of research over others or in redistributing federal support to accommodate the search for alternatives.

In the accompanying document we have summarized results from animal behavior research that have directly benefited the human conditon (pages 4 to 8). Included are examples of disease control and prevention, teaching strategies, space flight safety, and others that emerged from behavioral research in the animal laboratory. The issue is whether future solutions to many of our nation's health and economic problems that rest in behavioral approaches would be jeopardized by unintended consequences of the legislation.

Composition of Animal Studies Committee

The overall emphasis of H.R. 6928 is to minimize animal distress and discomfort. But terms such as distress and discomfort are empirically verifiable. That is, they are researched by scientists studying animal behavior. Researchers who study the emotional aspects of animal behavior have a great deal of scientifically based expertise to offer the animal studies committee of Title II. Yet, the composition of the committee as now written makes no provision for this expertise.

We suggest the composition of the committee be expanded to mandate a researcher in animal behavior. This would recognize that the animal studies committee is in large part concerned with the psychological well-being of animals, which is best evaluated by an animal behavior expert.

Title II as now written also mandates a lay member in the composition of the animal studies committee.. There is a fear among some researchers that the presence of a lay person on what resembles a research review committee could mean that unqualified judgments are being made about the merits of research. This concern appears to be based on the assumptions that (1) the lay person will have little or no understanding of research methodology; and (2) that the lay person will be an animal welfare advocate and therefore unsympathetic, perhaps even hostile, to any research involving the use of live animals. However, there are signs that these concerns are diminishing within the research community.

The topic of animal care committees was discussed in a panel during the annual meeting of the National Society for Medical Research, held on December 14, 1982. Representatives from a variety of institutions related their experiences in establishing or working with such committees. Judging from their remarks, it appears that the committees play an active role in many institutional research systems. But it is also clear that the composition and other characteristics of animal care committees vary greatly among institutions, primarily because the institutions themselves vary greatly. Our concern is that the proposed legislation is not sufficiently flexible to accommodate this diversity.

We suggest a more studied approach in determining the impact of the animal studies committee on animal welfare. It would be useful to gather what

information exists regarding participation of individuals on institutional animal care committees. For example, the inclusion of the lay person, while not a traditional concept, is not unprecedented. Depending on the number of such experiences, much of the information would aid in evaluating the impact of this requirement.

Ambiguous Terms and Exclusions

There are four basic requirements set forth in Title III upon which federal support for research "involving the direct use of conscious animals" would be contingent. Our understanding is these will require:

- that the research proposal must include a statement about the relative benefits of the reseach and anticipated level of animal distress;
- that there must be veterinarian review of procedures involving live animals;
- that anesthesia or tranquilizers must be used in surgical procedures and can only be withheld for scientific reasons "for the necessary period of time"; and
- that animals cannot be used "in more than one operative procedure from which it is allowed to recover" except in instances of "scientific necessity."

The debate here often centers on the ambiguity of two prominent phrases used in this Title: "direct use of conscious animals" and "scientific necessity." Those concerned primarily with the welfare of animals feel that the phrase "scientific necessity" is in effect an exemption that will allow harmful practices to continue. Researchers, on the other hand, feel that the bill's definition of "direct use of conscious animals," in the most narrow interpretation, could limit what usually are considered to be harmless procedures. The bill's definition is "any use that involves more than momentary minor pain or discomfort, or any procedure except where the animal is anesthetized throughout the entire course of that procedure" (Sec. 205(5)). In particular, the term "momentary pain" makes this an ambiguous definition because of the difficulty in measuring such a condition in any terms other than subjective ones. Interpretation therefore could vary from one institution to the next, which in turn could result in varying quality of review of laboratory animal use and care. Again, we recommend a closer examination of the issues which we believe would require a psychological perspective.

Finally, it should be noted by the Subcommittee that the exemption set forth in Title IV of H.R. 6928 have the appearance of diminishing, rather than promoting, animal welfare. In essence, this Title establishes a policy that at least some areas of research (farm and wildlife) are automatically justified in their use of animal subjects, even though within these categories there is a substantial amount of federally-supported research involving the welfare of live animals. Excluding these animals from the protections

established by this legislation has a deleterious net effect on animal welfare and to some extent negates efforts to accomplish the humane objectives of other portions of the bill.

Summary:

We believe there is a great need to more carefully consider what would be the actual impact of the provisions of this legislation. We recommend that, in its deliberations during the next session, this Subcommittee and others involved make a special effort to study the questions that have been raised in connection with this legislation. We would be pleased to assist in this effort in any way that we can.

APPENDIX C

ASSOCIATION for the ADVANCEMENT of PSYCHOLOGY

TESTIMONY OF

Perrie M. Adams, Ph.D.

Chair of the American Psychological Association's

Committee on Animal Research and Experimentation

on behalf of

THE AMERICAN PSYCHOLOGICAL ASSOCIATION

and

THE ASSOCIATION FOR THE ADVANCEMENT OF PSYCHOLOGY

before the

UNITED STATES HOUSE OF REPRESENTATIVES

SUBCOMMITTEE ON SCIENCE, RESEARCH AND TECHNOLOGY,

COMMITTEE ON SCIENCE AND TECHNOLOGY

Honorable Doug Walgren, Chair

on the subject of

USING ANIMALS IN RESEARCH AND TESTING

October 14, 1981

Mr. Chairman, members of the Committee,

My name is Dr. Perrie Adams. I am a professor of psychology at the University of Texas Medical Branch. I am testifying today as chair of the American Psychological Association's Committee on Animal Research and Experimentation.

The American Psychological Association, or APA, is the nation's major professional and scientific organization representing psychology. Together with its sister organization, the Association for the Advancement of Psychology, APA represents over 65,000 members and affiliates. The Committee on Animal Research and Experimentation is one of APA's oldest committees. It was established in 1925 and from its inception has been concerned with the welfare of animal research subjects. Clearly, our concern predates much of the current controversy in this area, and as our purposefully selected acronym -- CARE -- illustrates, we are sensitive to the issues of humaneness that are involved.

The Committee's stated responsibility, delegated to it by APA, is to "review the ethics of animal experimentation, and to disseminate guidelines for protecting the welfare of animals used in research, and to consult on the implementation of those guidelines." The guidelines referred to here have been continuously revised and upgraded by CARE over the past 30 years. Further, they are part of the enforceable standards of conduct for APA members, known as the Ethical Principles of Psychologists.

The Principles governing care and use of animals in research require that "the investigator insures the welfare of animals and treats them humanely." They go on to state that "a psychologist trained in research methods and experienced in the care of laboratory animals is responsible for insuring appropriate consideration of their comfort, health, and humane

treatment." Finally, it is mandated that "psychologists will make every effort to minimize discomfort, illness, and pain of animals. A procedure subjecting animals to pain, stress, or privation is used only when an alternative procedure is unavailable and the goal is justified by its prospective scientific, educational, or applied value."

This subcommittee is to be commended for conducting these hearings on the use of animals in research. The issues raised in this debate are emotional as well as scientific in nature, making consensus a difficult and elusive goal. APA has been addressing these issues for some time, and as the excerpts from our Ethical Principles illustrate, we fully support many of the goals of the various legislative proposals that have been introduced on this subject.

Yet, we feel we must point out that the assumptions on which we operate as scientists appear to be very different from the assumptions made by animal welfare advocates about the nature of animal research. We believe that the use of live animals in research and experimentation is essential in efforts to save lives and improve human welfare. Animal research is not designed to make animals suffer. It is designed to alleviate human suffering. Research goals do not focus on the scientific use of animals as an end point. Rather, research is focused on understanding and combatting medical, behavioral, and social conditions that are problems for the human race. To discontinue or severely dilute these efforts would deny the extraordinary history of breakthroughs that have resulted from research involving animals as experimental subjects.

Before citing specific examples of such accomplishments, let me again stress that we are in accord with the basic purposes of the legislation before this committee. If a research issue can be addressed effectively without the use of animal subjects, then we are <u>mandated</u> by our Ethical

Principles to pursue these alternatives. But the question that needs to be answered is whether the development of alternative methods of research and testing is too great an unknown on which to hinge policies as important as those under discussion during these hearings. Current research methods are not immune to change, but there must be a sound basis for rejecting them. The desire to exempt animals as research subjects compels many to believe that there are alternative research methods, but we cannot automatically assume that alternatives exist. That alternatives are not being used en masse does not signal a lack of awareness or sensitivity on the part of the research community, nor does it indicate a propensity to inflict harm on animal subjects. It may well accurately reflect the necessarily slow but deliberate search process for alternatives.

I raised the "unknowns" surrounding the development of alternatives. One of the most crucial of them is how much ongoing research we would lose in that pursuit. We cannot afford to put research on hold while alternatives are being developed. Yet, this is what has been proposed in the bills under consideration. For example, in H.R. 556, the so-called Research Modernization Act, it is proposed that the search for alternative methods of research be supported by transferring 30-50 percent of the total appropriations for federal research and testing programs involving live animals. Further, H.R. 556 would require agencies housing or sponsoring such programs to support training in the use of alternatives. The combined effects of these actions would be to divert funds from widely accepted and successful methods of research and direct them toward undiscovered and unproven alternative methods. As members of this subcommittee know too well, this is a time when economic resources available for research grants and training are already in grave

danger because of diminishing funds to the non-defense related federal budge. Not only does this affect the standing of the United States as a world leader in science, but more importantly, it jeopardizes the momentum in research toward solving or developing ways of coping with the myriad medical and social ills that affect humankind. Assessment of the damage and opportunity costs involved could never be made, but it is inconceivable that 30-50 percent of current research efforts involving the use of live animals could be adequately or quickly replaced by models and other methods of simulation that are not now available. The damage would be compounded by abandoning ongoing research in favor of the search for alternatives. Can we really afford to give up for the next generation the sorts of accomplishments that have come out of animal research in generations past?

Let me provide some examples of the accomplishments that have come from animal research in psychology. These findings might never have emerged under unduly restrictive laboratory animal regulations.

The majority of what we know about how people learn began years ago in psychological research laboratories based on studies using animal subjects. Such everyday concepts as reinforcement and reward emerged from carefully controlled animal studies that would not have been appropriate for human subjects, but that clearly have helped the human condition. For example:

- Biofeedback allows for the conscious control of what are usually automatic bodily functions, such as blood flow, heart beat, and muscle position. Today the technique is being used to effectively treat wideranging medical problems:

  Scoliosis is a disabling and disfiguring curvature of the spine. Biofeedback has been shown in ground breaking research to actually reverse the process;

  Applied to heart problems, biofeedback is used to teach cardiac patients to control their blood pressure, and, thus, significantly lessen the likelihood of future attack;

Applied to migraine headaches, insomnia, and low back pain, biofeedback is considered by many to be the treatment of choice. Thus, biofeedback is dealing with problems that not only plague millions of Americans, but cost American industry billions of dollars each year in employee absence and poor worker efficiency.

The use of all these medical treatments based on biofeedback began with psychologists interested in the conditioning of the autonomic nervous system of the rat.

- Programmed Instruction is the application of learning principles to standard educational tasks. Programmed instruction appears to be the future hope in effectively and efficiently training recruits in the armed services with increased savings in training costs. It also is being used in schools, colleges, and other institutions to teach reading and vocational training, and even selfhelp skills to the mentally retarded. The cost of programmed instruction compared to the traditional classroom setting is miniscule and the potential benefits, both social and economic, are enormous. But the technique would not have come about without basic research on the learning of sequential tasks by animals.

- Behavior Modification and Behavior Therapy are learning-theory approaches to changing how an individual acts in certain situations. The techniques would not have come to being without early and continuing psychological research on what influences animal behavior. Today, both have been documented literally hundreds and perhaps thousands of times in improving the lives of hospitalized mental health patients and in developing effective therapies for psychological disorders. The techniques also are gaining notoriety because of their successful application to problems of obesity, alcoholism, and drug addition.

  What has been less publicized is the effect of such behavioral programs in the industrial sector. For example, Emery Air Freight Company recently reported that a behavior modification program with its employees has increased its use of productive capacity from 45 to 90 percent, with savings of more than $2 million over three years. (Organizational Dynamics, 1973, 2, Winter, 41-50.)

  A behavioral program also has been used to teach job finding skills to the unemployed of our country. The cost of placement in this Job Finding Club, as the program has been called, was an incredibly low $167 per person and the participants in the program were twice as likely to secure and retain employment as those using other employment programs (Behavior Research and Therapy, 1975, 13, 17-27). The Job-Finding Club

concept has now raised considerable interest in the Department of Labor for use in placing clients who otherwise would be eligible for welfare (U.S. Department of Labor, Report No. DLMA-51-17-76-04, 1978).

Not only does this Club concept stem directly from principles of learning first investigated through animal research, but the job club's developer is one of the foremost animal learning psycholigists in this country.

- Research on animal learning has played a key role in America's space program. The recent successful voyage of the space ship Columbia has allowed us all to feel a proud sense of mastery over space, but it was only 20 years ago that we were looking at space with feelings of uncertainty and peril. Among our unanswered questions back then were whether and how well astronauts would perform in the space environment. We answered those questions in part by sending two chimpanzees on a trial mission. The chimps, Ham and Enos, were carefully trained by psychologists who specialized in animal learning. The chimps were sent into orbit, performed their complex tasks perfectly, and were safely returned to earth. Was the training they received from psychologists, and the costs of the trial flights worth it? Perhaps Senators Glenn and Schmidt could provide a better answer than I.

- Conditioned taste aversion is a learning technique in which eating a certain food is followed by a drug which produces an unpleasant reaction. This pairing of food and illness often results in the refusal to eat even a small amount of that food again. The effect was developed in the animal laboratory by psychologists interested in the psychophysiological mechanisms of taste in the rat, but its applications have gone far beyond the laboratory. Taste aversion has given new insight into the problems and solutions to problems of cancer patients undergoing radiation therapy. A severe problem in radiation therapy had been that patients simply would not eat sufficiently following treatments, compounding the debilitaling nature of the cancer, itself. Now, it is a common strategy to deliberately condition a cancer patient to avoid a certain food following radiation treatment so that the patient will eat other foods and maintain proper nutrition.

  A similar approach is used in treating anorexia, a condition in which young people starve themselves, sometimes to death. Again, a deliberate learned aversion is produced to one food that results in the eating of other foods.

  The same process has been used successfully in the field of agriculture. In California, coyotes and wolves are fed mutton laced with a drug to produce an unpleasant reaction. The result is that predators, without being harmed, are conditioned in one step to cease attacks on sheep, even though sheep have been preyed upon for generations. Estimates of savings in lost stock run in the millions of dollars. Similarly, in North Dakota there is now a program underway in which black birds are being conditioned by taste aversion to stay away from crops. The potential cost-savings of this project are enormous.

- In other learning theory applications of animal research, ongoing attempts to teach language skills to chimpanzees have led to new experimental techniques for teaching these skills to profoundly retarded, nonverbal children. In fact, a few months ago, a new research center opened in Atlanta where investigators are using chimps to develop language training methods that can be applied to such children.

- Desensitization is one of the most effective and straightforward psychological approaches for removing phobias and other debilitating fears, such as fears of flying, of certain animals, or of crowded places. As a result, this direct byproduct of basic animal research on the principles of learning allows otherwise apprehensive people to lead comfortable and productive lives.

- Behavioral research has shown that a phenomenon called learned helplessness occurs when an animal is placed in a stressful situation it cannot control. The finding is that the animal quickly gives up trying to escape. When later given the chance to escape, the animal will not overcome its helplessness unless it is forced to respond.

  The learned helplessness model has resulted in new insights into the causes and treatment of depression in humans. Ground-breaking research is now well underway to predict personality types most susceptible to depression, and to effectively deal with depression when it occurs, all based directly on the animal model.

The psychological research laboratory in which animal subjects are used has also given rise to important findings for humans that are not based solely on learning principles, but that are based in other less-well-known areas of psychology.

- The Karolinska Institute has this past week awarded its Nobel Prize to distinguished APA member Dr. Roger Sperry for "unlocking the secret of the brain." Sperry, working with animals, determined that the hemispheres of the brain are separate and communicate to each other in special ways only through a connecting band of fibers. The cutting of these fibers resulted in what might be characterized as two distinct brains both working independently within one animal. This research, again with the help of Dr. Sperry, has directly given rise to the understanding and treatment of a variety of severe neurological problems in humans, among them epilepsy, stroke, language disorders, and brain damage. It has also contributed immeasurably to our understanding of how normal brain development occurs.

- Behavioral teratology is the psychological study of drug exposure during pregnancy on the behavioral development of the offspring. Behavioral deficits uncovered in this area of study often are observed in the absence of any obvious physical abnormalities. In fact, the approach has been shown in animals to be much more sensitive than using physical abnormalities in predicting the harmful effects of drugs on a fetus. This finding

has resulted in the routine use of behavioral teratology to screen new drugs for safety before being given to pregnant women. Further, much of what we know about the risks of alcohol, caffeine, and smoking during pregnancy and their implications for birth defects and mental retardation stem from this behavioral work.

- The behavioral effects of drugs and chemicals on animals have been studied for the past 25 years to better understand the way drugs work, and to predict their toxic effects at a particular dosage. This psychological approach to examining drug effects has been particularly useful in classifying new drugs. For example, the distinction between major and minor tranquilizers is based on the behavioral responses of animals to these drugs. Also, much of the new exciting work on the opiates that are naturally present in the human brain was stimulated by observing the behavioral effects of these substances in animals. This work will ultimately allow us to develop new pain-relieving and mood-altering agents that work without the danger of drug addiction.

- Disorders of remembering are by far the most common impairments of the elderly, of those who suffer from senile dementia (Alzheimers' disease), of stroke victims, and head injury victims. These memory problems were commonly believed to result from injuries to memory traces, that is, to the parts of the brain that are modified by learning and experience. However, psychological experiments with animals that have suffered brain injuries have shown that there are few, if any such injuries which destroy memory traces. The studies suggest that the great majority of memory failures are due to impairments of access to memory traces that are latent, but intact. The implications of these findings for memory loss victims are now being vigorously pursued and new hormonal therapies based on these psychological studies are being developed.

- Psychologists who study animals attacking prey observe a type of paralysis that many times occurs in the prey called tonic immobility. Researchers are now using this result to develop a model of rape-induced paralysis in humans. This is among the first serious theoretical insights into the social problem of rape. The model has important implications for rape prevention, treatment and counselling of rape victims, and even the adjudication of accused rapists.

- The behavioral discovery that many animals convey information among themselves on the basis of chemical signals has lead to developments which have profound ecological implications for humans and animals alike. For example, the discovery and later synthesis of specific chemicals which insects use as sex attractants allowed scientists to chemically bait traps containing insecticides to control harmful agricultural pests without having to saturate the environment with large amounts of toxic and potentially harmful materials.

This list could go on, but other examples would only echo the theme of those listed here: Controlled psychological studies using animal subjects were required before a human problem could be adequately addressed and solved. We maintain that a carefully and humanely conducted series of animal studies is not too high a cost to pay for improving the human condition.

In conducting these hearings, the subcommittee is providing a much-needed forum for the debate on the experimental use of live animals. However, the subcommittee and Congress as a whole is being asked to set science policy based on one set of assumptions and views that virtually ignore or reject a number of relevant scientific and social questions that must necessarily be brought to bear. Therefore, we respectfully recommend that legislative actions of the kind that have been proposed be postponed in favor of a more balanced and deliberative examination of their effects on research and on society as a whole. Concern for the humane treatment of animals is the common denominator for all the parties involved. Let us look for constructive ways to build on this common ground so that the unintended consequences of hasty actions can be avoided.

Thank you for your attention. I would be pleased to respond to your questions.

AMERICAN FUND FOR ALTERNATIVES TO ANIMAL RESEARCH

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9 December, 1982

U. S. HOUSE OF REPRESENTATIVES
SUBCOMMITTEE ON HEALTH AND ENVIRONMENT
REPRESENTATIVE HENRY WAXMAN, CHAIRMAN
HONORABLE COMMITTEE MEMBERS

The American Fund for Alternatives to Animal Research urges that HR 6928 be reported out of subcommittee.

With regard to the costs of implementing the humane housing and other requirements of HR 6928, it is a question not of facilities and universities having too little funds, but of how they make use of the funds they have. I have many times visited a large university laboratory near my home in which the cages are barely large enough for the cats and dogs to turn around, and where dogs, an hour after heart transplants lie unattended on a none too clean floor. Chickens in this laboratory were crowded 10 to a 3 by 3 foot cage, yet there was was plenty of space in most of the animal rooms for humane quarters. Yet the corridors in the hospital section of this same building are at least 20 feet wide. I did not see the swimming pool for the staff here, but many university swimming pools are luculently luxurious, more so than most of their graduates could afford to use, once they leave. Many universities have expensive landscape gardening. It is inethical that laboratory animals should undergo additional suffering because their minimal comfort is ignored in the distribution of funds by university budget committees.

As to necessity for legislation, we have no way of knowing how many

laboratories besides the well known one at Silver Springs could be in a similar condition, because there are not enough Alex Pachecos to take jobs in each and bring the conditions before the public. Science, although very much to be respected, is an ethically neutral subject, so cannot always be relied upon to supply reasonable ethical restraints on animal research. Investigators in other fields, uncluding life-saving ones, also need and expect restraints in the use of their materials such as expensive library books and government documents, and these restraints rarely hinder their research.

Since regulation may not make a substantial reduction in the numbers of animals used, I am convinced that regulation needs to be combined with other approaches, This is where the responsible development of alternatives fits in. The international group with which the American Fund for Alternatives is associated, has funded funded development of alternatives for over 20 years. None of the promising research projects which it has supported were able to obtain funds through the normal channels, sometimes because they were innovative. Yet once given their start by the Air Chief Marshal Lord Dowding Fund, with the opportunity to show first results, most of these projects have continued with government or industrial support.[1]

Our American Fund for Alternatives in the United States has had the same experience since it was founded in 1977. As one example, Joseph Leighton M.D., Chairman of Pathology at the Medical College of Pennsylvania, is developing a replacement to the Draize eye irritancy test, a widely used and very painful assay, supported by one or our grants. The results that he has had so far have led several scientists to consider the method he is working on to be the most practical of the Draize replacements now being developed. Yet normal channels did not provide support for this project. Now that he has preliminary results, an industry has begun to assist him by providing chemicals for testing his method.

Another of our projects has been a chick embryo skin assay, developed

1. Documented in the Bulletin of the Lord Dowding Fund, London, 1973-

in conjunction with the Lord Dowding Fund. Now, a major laboratory at Ohio State University, among others, is using it in place of animals to test whether or not certain chemicals have caused cancer in cells onto which they were innoculated.

In order to replace animals in the various tests, there must be effort and funds aimed at finding valid alternatives. A variety of techniques are available which might be applied to specific tests in which animals are now used. But to validate these alternatives to animals takes time, personnel and money. Because technology keeps evolving at such a rapid rate, what seems impractical if not impossible today may become doable next month or next year.

The majority of society wants to continue a national biomedical research program, scientists want to open up new fields of discovery, and the animal rights groups want to eliminate all possible painful research and testing. By working together, ways can be explored to reconcile those apparantly conflicting aims. It will take a willingness to see differing points of view; it will take compromise without abandoning ideals, and most of all it will take an effort to see that there are common interests and that common ground for working out solutions does exist. Science and scientists need to look beyond the confines of animal experimentation. In some cases that kind of exploration will pay off handsomely.

Meanwhile, the combination of searching for alternatives to the use of either humans or animals in research, combined with a regulatory system to give them some protection as long as they are used, provides that ground which I think most of our population will gladly approve and support.

Ethel Thurston

Ethel Thurston Ph.D.
Director

ASPCA

America's First Humane Society

9 December 1982

Dear Representative:

The American Society for the Prevention of Cruelty to Animals (ASPCA) urges you to support H.R. 6928 and to act favorably on it during this session of Congress. The ASPCA submits this letter in support of H.R. 6928 and endorses the testimony submitted today by the Society for Animal Protective Legislation.

This bill, if passed, would serve to promote the development of nonanimal methods of research, experimentation and testing and could serve to improve the conditions of animals used for such purposes.

In order to accomplish this, H.R. 6928 authorizes the Secretary of Health and Human Services to award grants for research into the development of methods of nonanimal research, experimentation, testing and methods which reduce the number of live animals used for such purposes and which produce less pain and distress in such animals than the methods currently used. H.R. 6928 also authorizes the Secretary of Health and Human Services to direct federal agencies to coordinate their efforts to reduce the number of animals used for research, experimentation and testing, and to promote the development of nonanimal testing methods and the evaluation of existing nonanimal methods.

In addition, the Secretary is authorized to direct the National Toxicology Program to significantly increase its resources for research and development of nonanimal research and testing methods, and the Secretary is required to submit reports to the Speaker of the House and the President of the Senate describing these new initiatives to reduce animal use. Research entities will be required to establish animal studies committees that are responsible for reviewing the appropriateness of animal use in experimental research in order to be eligible to receive a federal award to conduct research, experimentation and testing involving the use of large numbers of animals.

H.R. 6928 is long overdue. Initiatives to reduce the use of animals for experimentation, research and testing should be encouraged as should research into methods that produce less pain in the animals that are used. Coordination of efforts by federal agencies to lessen duplication of work and unnecessary use of animals is sound policy that does not cause the sacrifice of scientific benefits. Rather, the establishment of animal studies committees to review the appropriateness of animal use fosters efficiency while at the same time reduces the chances that animals will be unnecessarily used or caused unnecessary pain and distress. And the inclusion in the animal care committee of one individual primarily responsible for representing community concerns regarding the welfare of animals used for experimentation, research and testing should result in a more careful review of policies and procedures than might be expected by self-policing. There are many qualified individuals, including professionals associated with the ASPCA and other large humane societies who would be willing and able to serve voluntarily on such committees.

Your support for H.R. 6928 is needed now. I sincerely hope that we can count on your favorable vote.

Yours very truly,

John F. Kullberg
Executive Director

Stanley Pruszynski
ASPCA Attorney

AMERICAN VETERINARY MEDICAL ASSOCIATION
WASHINGTON OFFICE – SUITE 828
1522 K STREET N.W. • WASHINGTON, D.C. 20005 • PHONE: AREA CODE 202 / 659-2040

December 10, 1982

The Honorable Henry Waxman, Chairman
Subcommittee on Health and the Environment
Committee on Energy and Commerce
U.S. House of Representatives
2415 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Waxman:

We would like to comment on H.R. 6928 and request that this letter be made a part of the record of the December 9 hearings of your subcommittee regarding that bill. We also wish to encourage favorable action on the bill by the subcommittee.

Senator Melcher, in his statement to the subcommittee, commented on the current position of the American Veterinary Medical Association. We would like to confirm his comment and expand on it briefly.

The AVMA had, until very recently, believed that the Animal Welfare Act provided an adequate legal basis for regulation of the humane care of animals in research and testing institutions. The Department of Agriculture, we thought, should be adequately funded to appropriately enforce the Animal Welfare Act, and we have expressed those views to the appropriations committees. Recently it has become apparent to us that the Department of Agriculture is not likely to be adequately funded for this purpose for several reasons, so we now join with others who believe new authority is needed to help assure appropriate care of laboratory animals.

We have been concerned, as we saw various proposals to stimulate the development of alternates to the use of animal models in research and testing. While we wholeheartedly support the concept of developing and using alternate methods, we are doubtful that much can be done to provide added stimulation for developing them. Most of the useful alternatives have developed in the course of conducting research to solve other problems. We believe that the cost of laboratory animals, the cost of keeping them, and the problems of working with them are the most effective possible means of stimulating the development of alternatives. While we do not oppose the parts of H.R. 6928 dealing with this subject, we doubt that it can have much effective impact.

We believe that there is a need for assuring compliance with the National Institutes of Health Guide for the Care and Use of Laboratory Animals and that H.R. 6928 or S. 2948, if either were amended as proposed by Senator Dole's amendment No. 3630, would provide a basis for such assurance. The various current estimates of the costs of rapidly coming into compliance with the NIH guidelines are apparently not widely accepted. Senator Dole's proposal of a careful study of such costs, and regulation based upon the findings of the study, provides reasonable assurance that biomedical research progress will not be curtailed by excessive costs of compliance with the accreditation or certification requirements.

We recommend your consideration of an amendment to H.R. 6928 similar to the one proposed by Senator Dole for S. 2948. We further recommend that, with such amendment, H.R. 6928 be reported and recommended by the Committee on Energy and Commerce.

We appreciate this opportunity to comment on this legislative proposal which we believe will help improve the care and treatment of animals which are essential to the advancement of biomedical knowledge and the safety of many consumer products.

Sincerely,

W. M. Decker, D.V.M.
Washington Representative

xc: Members of the
Subcommittee

22 East 38th Street,
New York, N.Y. 10016,
6 December 1982.

S i r:

Enclosed is a copy of a petition signed by 564 concerned citizens in this area who are strongly opposed to H.R. 6928/S. 2948. The original petition has been sent to my own Congressman, Mr. Green.

In addition to the ten objections listed on the enclosed petition, we object to the role which would be played by the American Association for the Accreditation of Laboratory Animal Care under the proposed bill. A glance at the history of the A.A.A.L.A.C. provides ample justification for such concern. During the 1960's, when humane groups were working for the passage of the Animal Welfare Act, the A.A.A.L.A.C. was founded by the commercial laboratory animal industry in order to prevent passage of that bill. The idea was that the animal research industry was regulating itself, and so no Government regulation was needed. This ploy failed, and the Animal Welfare Act passed anyway, but the A.A.A.L.A.C. continued in operation.

There is not a shred of evidence that experiments performed in A.A.A.L.A.C.-accredited laboratories are any whit less cruel than those taking place in other laboratories. The A.A.A.L.A.C. is primarily set up to provide a smokescreen for the experimenters to hide behind.

I enclose a letter written to me by Avon, in which Avon informs me that their laboratories are accredited by the A.A.A.L.A.C. and so there is nothing to worry about. In spite of these soothing assurances, a report obtained through the Freedom of Information Act (one of the few ways concerned citizens can find out what is really going on in the secrecy-shrouded laboratories) provides the information, not mentioned by Avon, that cosmetic tests on rabbits' eyes (the famous -- or infamous -- Draize test) were responsible for pain that was unrelieved by anesthetics, pain-killing drugs, or even tranquillizers.

The A.A.A.L.A.C. is thus not a responsible organization. Moreover, it is composed of persons who are making money from the breeding, importation, and sale of laboratory animals, and persons closely associated with such vested interests, who are not the people to whom one should look for the protection of animals from cruelty. The soothing "assurances" with which H.R. 6928/S. 2948 is replete are nothing more than a red herring designed to mislead and deceive concerned citizens.

H.R. 6928/S. 2948, like the Animal Welfare Act, contains a treacherous loop-hole to the effect that anesthetics may be withheld if the experimenters simply state, without proof, that such omission is necessary. This provision will be just about as effective as a law declaring that theft is illegal--except when the thief claims that such theft is necessary.

For all these reasons, we are vigorously opposed to H.R. 6928/S. 2948, which one national animal welfare society has appropriately described as "the slickest sell-out in the history of animal welfare."

I request that this letter, together with one page of the enclosed petition, be included in the printed record of the hearings on H.R. 6928.

Respectfully yours,

Thomas G. MacGowan, Jr.

Thomas G. MacGowan, Jr.

Enclosures:

(1) Letter from Avon to me, dated March, 1979, stating that Avon is accredited by the A.A.A.L.A.C.
(2) Form filed by Avon with the U.S.D.A. stating that painful tests were performed on the eyes of unanesthetized rabbits by Avon
(3) Copy of petition signed by 564 people against H.R. 6928

The Honorable
Henry Waxman
Chairman
Subcommittee on Health and the Environment
of the Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

AVON

Avon Products, Inc., Nine West Fifty Seventh Street, New York, N.Y. 10019

See p. 2

March 8, 1979

Mr. Thomas G. MacGowan, Jr.
22 East 38th Street
New York, NY 10016

Dear Mr. MacGowan:

Thank you for writing to us about Avon's testing of its products on animals, for the safety and protection of consumers.

Avon has a responsibility to insure that all products are as safe as we can make them for human use, and as harmless as possible under reasonably foreseeable conditions of possible misuse.

To meet this responsibility, each Avon product undergoes a sophisticated series of tests. A part of our testing program requires the use of laboratory animals. Before any product, particularly a new formulation or ingredient is allowed to be used by a human being, it is first tested on rodents and rabbits in our laboratories. We want to be sure that the product will be as gentle, mild and safe as possible.

Although cosmetics and toiletries are not intended to be ingested, experience tells us that this may happen, particularly with young children. Testing with our laboratory animals assures us that in the event of product misuse among young children, our products will produce only minor and temporary reactions in most cases.

All cosmetic companies are required by the Food & Drug Administration (FDA) to conduct all tests necessary to substantiate the safety of products. The tests we perform follow the methods referred to in a 1975 FDA regulation concerning the adequate safety substantiation of cosmetic products. Tests are on file at Avon for FDA inspection at any time.

Although the FDA does not specifically state that we must test on animals for this substantiation, it is mandatory that we do toxicological tests, which implies animal testing because we have not been given any authority to conduct toxicity tests on human beings.

An Avon customer, who wrote to the FDA, sent us the reply she received from the Acting Director, Office of Consumer Inquiries, FDA:

"Numerous human case histories involving products found to produce or strongly suspected of producing adverse effects have been documented...These adverse effects could have been predicted if the appropriate animal tests had been done and correctly interpreted beforehand...Currently, animal tests are indispensable

for this purpose. Model predictive systems and in vitro (artificial environment) test are being developed. There is hope that in the future, tests with live animals can be minimized as a deeper understanding of toxicological phenomena permit us to rely more on in vitro tests. But for the moment, we have to depend primarily on live animal-bioassays for the detection of most of the toxic phenomena which humans and animals share in common when exposed to chemicals of external origin."

Our Research Laboratory is supervised by a staff of professionals who have advanced degrees in the Biological sciences and are trained in the humane treatment and care of animals. In addition, a Veterinarian is retained by Avon to inspect our Laboratories on a monthly basis to insure continuing compliance with the Department of Agriculture guidelines.

Avon's Laboratories are accredited by the American Association for the AAALAC! Accreditation of Laboratory Animal Care. To maintain this accreditation we must abide by their strict rules and regulations which require the humane handling, care, treatment and transportation of animals. Annual Laboratory inspections are also carried out by United States and State Departments of Agriculture.

Many of the statements made in articles do <u>not</u> pertain to Avon and are <u>absolutely not reflective</u> of the way in which Avon conducts its animal testing. For example:

- The rodents used in our laboratories are not force-fed to the point of internal organ rupture. Maximum dosage levels are set and not exceeded.
- Stocks are rarely used by Avon to hold animals in place and if required are used only for very brief periods of time. Animals have free access to water and food during each test day.
- Products placed in the eyes of rabbits to check irritation are either naturally expelled from the eye or are followed by a rinse of the eye. (The rinsing step stimulates normal action taken by a consumer should a cosmetic product get into the eyes.) Products <u>do not remain for days</u> in the animals' eyes.

Some companies who state that they do not test on animals are telling the truth as they see it. However, they send their products to independent testing laboratories, who do use animals in testing. Inasmuch as a company is not permitted to test products for toxicity on humans, this testing must be done on animals.

We want to assure you that in conducting tests on animals, Avon gives the highest consideration to both the welfare of the consumer and the humane treatment of the animals.

Sincerely,

Marion Mann

Marion Mann, Manager
Consumer Information Center

MM:ss

This report is required by la... Failure to report according to the regulations can result in an order to ... and to be subject to penalties as provided for in Section 2150.

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
VETERINARY SERVICES

ANNUAL REPORT OF RESEARCH FACILITY

(Required For Each Facility (Site) Where Animals Are Held)

RCS # 34-VS-56

1. DATE OF REPORT: October 4, 1978

FORM APPROVED OMB NO. 40-R3777

2. HEADQUARTERS RESEARCH FACILITY *(Name & Address, as registered with USDA, include Zip Code)*

Avon Products, Inc.,
Toxicology Department
Division Street
Suffern, New York 10901

INSTRUCTIONS: **Reporting Research Facility** *(Site)* complete items 1 through 24 and submit to your Headquarters Facility. Attach additional sheets if necessary.
Headquarters Facility complete items 25 through 27 and submit on or before February 1 of each calendar year to the Area Veterinarian in Charge for the State where the research facility headquarters is registered.

3. REGISTRATION NO.: 21-50

4. REPORTING FACILITY *(Name and Address, include Zip Code)*

Avon Products, Inc.
Biological Laboratory
Division Street
Suffern, New York 10901

REPORT OF ANIMALS USED IN ACTUAL RESEARCH OR EXPERIMENTATION

Section 2.28 of Animal Welfare Regulations requires appropriate use of anesthetics, analgesics, and tranquilizing drugs during experimentation. Experiments involving necessary pain or distress without use of these drugs must be reported and a brief statement explaining the reasons.

ANIMALS COVERED BY ACT	NO PAIN — Number of Animals Used Where No Pain, Distress, Or Use of Pain Relieving Drugs Was Involved.	PAIN AND DRUGS — No. Animals Involving Pain or Distress Where Appropriate Anesthetic, Analgesic, or Tranquilizer, Was Used	PAIN - NO DRUGS — No. Animals Involving Pain or Distress Without Use of Approp. Anesthetic, Analgesic, or Tranquilizer, *(Attach brief explanation)*	TOTAL
A	B	C	D	E
5. Dogs	1978 None used in	---	---	0
6. Cats	None used in 1978	---	---	0
7. Guinea Pigs	2424	0	0	2424
8. Hamsters	410	0	0	410
9. Rabbits	3248	0	487*	3735
10. Primates				
Wild Animals *(Specify)*: 11.				
12.				
13.	*Safety Testing (Draize Eye Irritancy Test) of all cosmetic products required by FDA Use of Anesthetics, Analgesic, or Tranquilizing Drugs would interfere with test results.			
14.				
15.				

CERTIFICATION BY ATTENDING VETERINARIAN OF RESEARCH FACILITY OF INSTITUTIONAL COMMITTEE

I *(We)* hereby certify that the type and amount of analgesic, anesthetic, and tranquilizing drugs used on animals during actual research or experimentation was deemed appropriate to relieve all unnecessary pain and distress for the subject animals.

16. SIGNATURE OF ATTENDING VETERINARIAN	17. TITLE	18. DATE SIGNED
Herbert J. Macchia DVM	Consultant Veterinarian	October 4, 1978
19. SIGNATURE OF COMMITTEE MEMBER	**20. TITLE**	**21. DATE SIGNED**
Yale Gresel Ph.D	Director - Product Safety & Information	10/4/77
22. SIGNATURE OF COMMITTEE MEMBER	**23. TITLE**	**24. DATE SIGNED**

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

I certify that the above is true, correct, and complete and that professionally acceptable standards governing the care, treatment, and use of animals including appropriate use of anesthetic, analgesic, and tranquilizing drugs, during actual research or experimentation are being followed by the above research facilities of sites (7 *U.S.C Section 2143*).

25. SIGNATURE OF RESPONSIBLE OFFICIAL	26. TITLE	27. DATE SIGNED
X Yale Gresel	Director of Product Safety and Information	10/4/77

VS FORM 16-23 (1/77) PREVIOUS EDITIONS MAY BE USED

PETITION TO CONGRESS

We are very much concerned about the massive cruelties of animal experimentation and about the need for effective, well-drafted legislation for the rectification of this abuse by the development of modern alternatives which do not involve live animals. We are, however, strongly opposed to H.R. 6928 and S. 2948, the so-called "Humane Care and Development of Substitutes for Animals in Research Act," because:

1) It is primarily a "facilities and animal models for human disease" bill which will speed the growth of animal experimentation;

2) An estimated half BILLION dollars will be required to fulfill its provisions for new animal rooms and laboratories;

3) It provides for training in animal "care," but not for training in non-animal research;

4) It provides for the protection of animals before and after, but not during, actual experimentation;

5) It permits the omission of anesthetics and the use of paralytics such as curare if the experimenters claim such omission is "appropriate";

6) It permits unrestricted, open-ended vivisection of zoo animals, farm animals, race horses, greyhounds, and gives carte blanche to military and space experimenters to do anything they like to animals, including the atrocities of atomic, biological, and chemical warfare research and the horrors of the SPACELAB experiments;

7) It contains no effective enforcement mechanism and relies on "self-regulation" by the vivisectors;

8) It contains no funding, not one penny, for alternatives -- just some pious verbal platitudes;

9) It will result in the production of more agonized "animal models of human disease and injury," and will have the net effect of more cruelty, not less; and

10) The only anesthesia in this bill is ANESTHESIA FOR THE PUBLIC.

THEREFORE, WE, THE UNDERSIGNED, regard this bill as a worthless sell-out and a cynical whitewash, and we request that you vigorously oppose it. It is worse than no bill at all.

Name	Address	Zip Code
[illegible]	129 2d Ave NYC	10003
Pianigiani Fabi.	158-18 Riverside Dr. West Apt 7H	10034
Mary [illegible]	41 King St 2R NYC, NY	10014
[illegible] Moore	535 E. 6th St.	10009
[illegible] Dale	[illegible] St Somerville NJ	08876
[illegible]	[illegible] CANADA	
Carol Anderson	21-61 Steinway St Astoria NY	11105
Lloyd Horne	147-14 84th Rd Briarwood, N.Y.	11435
Robert [illegible]	58 E. 3rd St. N.Y.C.	10003
Charles [illegible]	350 65th Apt 321	11220
Paul Stafford	555 Edgecomb Ave	10032
Edith B [illegible]	45 W 60th Street	10023

[Whereupon, at 12:49 o'clock p.m., the committee adjourned.]